UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA,

v. 20 Cr. 160 (MKV)

LISA GIANNELLI,

Defendant.

Trial

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New York, N.Y.
May 2, 2022
9:45 a.m.

Before:

HON. MARY KAY VYSKOCIL,

District Judge

APPEARANCES

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York
BY: SARAH MORTAZAVI
BENJAMIN A. GIANFORTI
Assistant United States Attorneys

FASULO, BRAVERMAN & DiMAGGIO, LLP
Attorneys for Defendant Giannelli
BY: LOUIS V. FASULO
-and-
ALEX S. HUOT

Also Present: Karline Jung, USDA Paralegal

Mattison Stewart, Defense Intern

(Trial resumed; jury not present)

THE COURT: Good morning. Please be seated, everyone. Good morning. I hope everyone had a nice weekend. Do we have anything we need to talk about?

MR. FASULO: Just one thing, Judge. Because of the volume of the materials, the Court is more than aware of the terabytes and petabytes, Mattison is one of our interns. She's been helping to help organize. I wanted the Court's permission for her to sit at counsel table.

THE COURT: Sure. Good morning. Thank you. That's fine Mr. Fasulo.

And nothing from you, Ms. Mortazavi?

MS. MORTAZAVI: No, your Honor.

THE COURT: All right. Our jurors are all here and ready to go and Ms. Dempsey will go and bring our jurors out. And you are going to be calling a witness right away.

MS. MORTAZAVI: Yes, your Honor. That will be Dr. Bowman.

(Continued on next page)

(Jury present)

THE COURT: Good morning, ladies and gentlemen. I hope you all had a nice weekend. We certainly had beautiful weather, not like this gloomy day today. I think we are ready to proceed, so Ms. Mortazavi or Mr. Gianforti.

MS. MORTAZAVI: Yes, your Honor. The government calls Dr. Jean Bowman.

JEAN BOWMAN,

called as a witness by the government,

having been duly sworn, testified as follows:

THE DEPUTY CLERK: State and spell your name for the record.

THE WITNESS: My name is Jean Bowman, and it's spelled J-E-A-N, last name B-O-W-M-A-N.

THE COURT: Thank you.

Ms. Mortazavi.

DIRECT EXAMINATION

BY MS. MORTAZAVI:

Q. Good morning, Dr. Bowman.

A. Good morning.

Q. Could you tell us where you are employed?

A. I'm employed at the FDA Center for Veteran Medicine.

Q. Dr. Bowman, I ask you to just adjust the mic.

Could you just repeat the answer that you gave to make sure everyone heard you?

A. Yes. I'm employed at the FDA Center for Veterinarian Medicine.
Q. Is that sometimes referred to as FDACVM?
A. Yes, it is.
Q. What's your current title there?
A. I'm a veterinarian medical officer.
Q. What sort of work do you currently do?
A. I work in, until a few weeks ago, it was called the division of the surveillance and the office of surveillance and compliance. We're now the division of drug compliance, and my work there involves providing scientific support to enforcement actions that are taken by the center.
Q. What are enforcement actions?
A. Enforcement actions can be things like warning letters, advisory letters, seizures and injunctions generally related to poorly manufactured or unapproved animal drugs.
Q. And what exactly is being enforced in an enforcement action?
A. We are enforcing the Federal Food Drug and Cosmetic Act and implementing regulations.
Q. Does the FDACVM where you work focus on animal drugs?
A. Yes, they do.
Q. Are animal drugs regulated by the FDA?
A. Yes.
Q. Are there different regulations applicable to animal drugs

versus drugs intended for human use?
A. Yes, some are the same. Most are different.
Q. For approximately how long have you worked at the FDACVM?
A. I worked there for over 32 years.
Q. Generally speaking what is the FDA's mission as it relates to animal drugs?
A. Our mission is to make sure that there are safe and effective animal drugs available for use for the treatment of animals and to prevent drug residue in human food.
Q. Are you a licensed veterinarian?
A. I am.
Q. What state are you licensed in?
A. I'm licensed in Maryland.
Q. Could you tell us your educational background?
A. Yes. I have a bachelor of science in animal science from the University of Maryland College Park and I have a doctorate in veterinary medicine from Virginia Tech, Virginia Maryland College of Veterinarian Medicine.
Q. Were you employed between college and veterinary school?
A. Yes, I was.
Q. Whereabouts?
A. I was employed by the University of Maryland Horse Research Center.
Q. What sort of work did you do there?
A. I was responsible for all types of general care of the

horses as well as helping the professors that were doing research there; collecting samples, maintaining records, providing follow-up to any injuries or treatments that the veterinarians prescribed for the horses.

Q. Were you supervised by anyone?

A. Yes.

Q. Who?

A. Norman Luban.

Q. What position did he hold?

A. He was the farm manager.

Q. What year did you start veterinary school?

A. 1985.

Q. And what year did you graduate?

A. 1989.

Q. What did you do for work after you graduated?

A. I started working right away with another practitioner in the equine practice. The type of practice you tend to call a farm call practice. We go to people's facilities and farms and treat the animals on site, and then I applied and also accepted a position with the Center for Veterinary Medicine.

Q. In that farm call practice that you just described, can you explain some of the work that you engaged in?

A. So we were responsible for routine heart health as far as deworming, giving vaccination, treating lamenesses, diagnosing problems, doing physical exams and history of patient that

presented within the problem and then providing a diagnosis, sometimes ordering diagnostic test to get the vac diagnosis and then prescribing treatment.

Q. Have you heard of the term "medical record"?

A. Yes.

Q. What is that term?

A. It reflects the records that a veterinarian is obligated to keep on each patient regarding that patient's history, any problems that its had, any visits that it required, any treatments that were recommended or given.

Q. And while engaged in that farm-call practice, did you maintain medical records?

A. Yes, we did.

Q. You mentioned that you had joined the FDACVM at around the same time you joined the farm-call practice?

A. That is correct.

Q. Did you join in 1989?

A. Yes.

Q. When you first joined the FDACVM, what position did you hold?

A. I was a veterinary medical officer in the office of new animal drug approval.

Q. What sorts of duties did you have in that role?

A. In that role we worked with drug companies to develop a plan for getting the drugs they wanted to get approved,

approved. They have to collect data for safety and effectiveness, as well as complete technical sections in several other areas, such as manufacturing and labeling.

So we worked directly with the drug companies and then reviewed the data that was generated to ensure that those products met our standard of safety and effectiveness before they were approved.

Q. Was there a point at which you transferred to a separate office within the FDACVM?

A. Yes.

Q. Approximately when was that?

A. 2008.

Q. What division was that?

A. That was the division of compliance in the office of surveillance and compliance.

Q. Is that the office where you currently work?

A. Yes.

Q. Focusing on your current position, is there a particular focus to your duties and responsibilities within the division of enforcement?

A. So my duties are involving providing scientific support for enforcement action. I also help collect evidence and organize evidence for cases that we're initiating in-house, and at times we also make referrals to the criminal side of FDA if we can't gain compliance with a firm.

Q. And apart from the professional experience that you've just described, have you any experience with horses beyond the farm-call practice you mentioned and your work with the FDACVM?
A. Yes, I've been a horse owner since I was 11, and to this day I currently have three horses that are pleasure horses, life shown and trail ridden and went through 4H on my horses, always had a deep activity with the horses in all different ways.
Q. Do you race horses?
A. No.
Q. Have you ever entered a horse in a horse race?
A. No.
Q. Have you ever attended any conferences having to do with veterinarian client/patient relationship?
A. Yes.
Q. Could you describe that?
A. There was -- because of COVID-19 and kind of a rapidly changing world of the use of video appointments for people, there was a lecture presented at the AAEP conference, the American Association of Equine Practitioners in December of 2021 on that topic regarding equine practitioners.
Q. Dr. Bowman, have you testified on behalf of the FDACVM before?
A. Yes.
Q. Have you ever been qualified as an expert witness before?

A. Yes.

MS. MORTAZAVI: Your Honor, at this time the government moves to qualify Dr. Bowman as an expert regarding FDA new animal drug approval and enforcement processes and the standards for veterinarian practice.

THE COURT: Mr. Fasulo.

MR. FASULO: No objection.

THE COURT: She will be deemed qualified in those areas.

BY MS. MORTAZAVI:

Q. Dr. Bowman, you mentioned that in a prior position you held as a veterinarian officer, you were apart of the FDACVM new animal drug approval process; is that right?

A. Yes.

Q. What does the FDA consider an animal drug?

A. An animal drug is substance or they call it an article in the act, and article that is intended to treat, diagnose, cure, mitigate the symptoms of any abnormal condition in the animal, apart of any of those defined substances or effective structure and function of the animal.

Q. Can those drugs be either prescription or over-the-counter just like human drugs?

A. Yes.

Q. Can you give us an example of those prescription drugs?

A. Phenylbutazone.

Q. Is that sometimes called Bute?
A. Yes.
Q. Have you heard of Banamine?
A. Yes.
Q. Is that a prescription drug?
A. Yes, it is.
Q. Have you heard of pentosan?
A. Yes.
Q. Is that a prescription animal drug?
A. That is not an approved animal drug. It is an approved human drug in an oral form for irritable bladder symptoms, but it's not approved in the United States for use in horses.
Q. As part of the FDA's drug approval process, does a drug have to be approved for a particular species?
A. Yes. However, under 21 CFR 530, there are conditions for which a drug may be used for off label, an approved drug.
Q. Can you give us an example of an over-the-counter animal drug?
A. So an over-the-counter animal drug would be something like ivermectin paste dewormer for horses.
Q. How is ivermectin administered?
A. That particular ivermectin is an oral product.
Q. How is Banamine administered.
A. Banamine is administered by injection.
Q. What about phenylbutazone?

A. It can be administered by injection or orally. It comes in tablets and in an injectable formulation.

Q. Have you heard the term API?

A. Yes.

Q. What does that mean?

A. An API is the active pharmaceutical ingredient of a drug.

Q. Can you give us some examples of APIs?

A. I already described phenylbutazone. Phenylbutazone is the active pharmaceutical ingredient in a couple of approved products. Banamine is the active pharmaceutical ingredient in flunixin meglumine.

Q. What about toltrazuril?

A. Toltrazuril is not approved in the United States for any animal use or human use and it is an active pharmaceutical ingredient.

Q. What about Diclazuril?

A. Diclazuril is an active pharmaceutical ingredient, and it is an active ingredient in at least I think two approved animal drugs.

Q. What about erythropoietin?

A. Erythropoietin is an endogenous, which means your body produces it. It's a hormone that increases blood cell formation.

There is medical formulation of that, that's not exactly the same, it's called Epogen. It's approved for use in

humans, but not animals.

Q. What does the FDACVM look to in determining whether a substance is a drug?

A. We generally look to the intended use. If a drug is listed in the official pharmacopoeia of the United States, the USPUS pharmacopoeia, that is also a way that we can determine that a product is a drug.

But if the intended use is something that obviously meets that definition of an article that's intended to treat, cure, prevent, diagnose a disease or abnormal condition, or it has effective structure of function and it's not a food, then it qualifies as a drug.

Q. What sorts of records does the FDACVM look to determine the intended use for a drug?

A. We tend to start with the label and the labeling, so the labeling can be printed labeling that is not on the package of the drug, but is handed to you perhaps when you purchase the drug, or it can be the website where you can purchase a drug, all the information on the website constitutes labeling.

Q. What about brochures or promotional material?

A. That can also be labeling.

Q. What about oral statements by the manufacturer's representative?

A. That can definitely be evidence of intended use.

Q. What about the name of the product itself?

A. At times, yes.
Q. To what extent does the chemical content of the substance matter in determining whether or not it is a drug?
A. It depends. If that's the best evidence we have that it is intended to be used as a drug, it's the formulation in which it's presented and the active ingredient, then we can use that; however, we prefer to use evidence of intended use.
Q. So can the FDACVM conclude that something is a drug without conducting any drug testing?
A. Yes.
Q. We discussed API a moment ago. What if a product contains no API, but there are claims made that it would treat a particular disease, would that still be considered a drug?
A. Yes.
Q. What is considered a new animal drug?
A. A new animal drug is an animal drug that is not generally recognized as safe and effective by experts in the field, so most drugs actually qualify as new animal drugs.
Q. Can you walk us through the process for obtaining FDA approval for a new animal drug?
A. So there's seven technical sections that firms have to complete in order to get their drug approved, that includes an animal safety section that would be completed in each species for each indication that a firm was interested in having on their label.

Then there's an animal safety section or they're required to do studies to show that the drug is safe at the dose administered, and kind of what the range of safety is so that we can develop a label that will allow the user to know whether an overdose is deadly or whether there's going to be an adverse event if you guess the animal weight wrong or treat the animal improperly. All that information has to go on the label eventually.

Then there's the manufacturing control section which is all about the manufacturing of the drug where the firm has to lay out step by step the entire manufacturing process, identify the facilities, where it's going to be manufactured, however many facilities that is -- and quite often it's more than one -- they have to identify and provide testing on all the ingredients that are going to go into that product. And those become the sources, the approved sources of that drug. If that needs to change, then they have to change that in a supplement application.

Then there's the labeling section. There's the environmental section. And if it's a food animal drug, there's a section on human food residues, and finally there's an all other information section.

Q. How long can the process take for getting a drug approved?

A. It can take multiple years. And rough guess, three to ten.

Q. What are the terms "safe" and "effective" mean in the

context of a new animal drug?
A. So A new animal drug is safe and effective when it's used according to the labeling. It's considered -- so it's not generally recognized as safe and effective.
It's only safe and effective within the confines of that approved application. So as long as it's being manufactured in a way that was described at the facilities that were identified and those facilities have all been inspected, and then that drug is used in accordance with the label directions, then it's expected to be safe and effective for that intended use.
Q. Can you give a hypothetical example for drugs that would be considered ineffective given its intended use?
A. So if you gave the intended use is to treat an eye infection, but you gave a dewormer, then we would not expect that to be -- is that what you meant?
Q. Yes.
A. Okay. Then you would not expect to get any effectiveness on that because you're not using the right product.
Q. Can you now give us a hypothetical example of a drug that would be considered unsafe given its intended use?
A. An approved drug?
Q. Any drug.
A. The best example I can think of off the top of my head is the current use in humans of ivermectin as a treatment for

Covid. It's an approved drug, but that's not its use and it would be unsafe for that purpose because it doesn't work.

Q. What is the FDACVM's role in the process of reviewing data regarding safety and efficacy as part of the new animal drug approval process?

A. As a veterinarian medical officer and a primary reviewer in that office, I was responsible for reviewing the data that was generated. We work in combination with statisticians and other specialists if needed.

But generally, I would review all that safety and effectiveness data and determine whether it met the standards that were required to be substantial.

Q. And the new animal drug approval process you described, does that apply for both prescription and over-the-counter drugs?

A. Yes, it does.

Q. And if I refer to over-the-counter drugs as OTC drugs, will you understand what I'm referring to?

A. Yes.

Q. Are there any differences in the approval process between prescription drugs and OTC drugs for animals?

A. No, there isn't.

Q. What about as part of the labeling process?

A. So the labeling process is different between prescription and non-prescription, but sometimes that distinction isn't made

for a drug until it's late into its approval process.

After we've evaluated the safety and effectiveness data and we've determined whether it would be appropriate for labeling it as an over-the-counter or a prescription drug, so that comes later.

And the labeling for a prescription drug is required to bear a different -- well, let me start with those, the over-the-counter drugs.

The over-the-counter drugs are required to have adequate directions for use by the layperson. As long as they can write adequate directions to be used by a layperson, the drug can be approved as an OTC drug.

Prescription animal drugs are required to have -- are not appropriate for adequate directions for use by the layman for multiple reasons why that is, and their labeling is required to bear a special statement that say, "caution." This drug is -- federal law restricts this drug to use by or on the order of a license veterinarian.

And then their standard for the rest of that label, it has to provide substantial -- that might not be the exact word that they use, but it has to provide sufficient information for the safe use of that product as labeled.

Q. What does a company have to show in order to establish that its drug is safe and effective?

A. They have to do multiple efficacy studies to demonstrate

safety under a variety of conditions of use for that indication and that species, often regionally.

They do studies in different regions of the country underneath different clinical investigators, and then they have to show safety in a number of safety studies from a 10 ex-overdose study, to a 1, 3 and 5 ex-overdose study, and then the additional data is collected at the use level in the efficacy study to substantiate safety.

Q. And, Dr. Bowman, you mentioned as one of the technical requirements of process, a firm will have to show their manufacturing process; is that right?

A. Yes.

Q. Why do they have to establish how they're going to be manufacturing a particular drug?

A. It can make the difference between the drug being effective and safe and not. Something as simple as with tablets, how hard those tablets are pressed can make a difference in the absorption of the drug from the stomach or the intestines; and therefore change the blood levels making the drug more or less effective, or more less toxic, so it becomes imperative that they follow all of those manufacturing processes that were approved.

Q. Have you heard the term CGMP?

A. Yes.

Q. What does that stand for?

A. That's the current good manufacturing practices.
Q. And what issues, if any, could arrive if a drug is not manufactured in conformance with current good manufacturing practices, besides what you just mentioned about pills being pressed?
A. The drug could wind up --for a sterile drug, it might not be sterile if it's not manufactured properly, which could lead to very serious complications in the patients that it's given. It could wind of having a different concentration, not being safe on any number of levels.
Q. Assuming a manufacturer did not comply with CGMP, how would that impact the approval process for a new drug?
A. That drug would not get approved.
Q. And what measures, if any, does the FDACVM take to ensure that firms are complying with CGMP?
A. They're regularly inspected both pre-and post-approval for the lifetime of that drug. They have routine inspections, often annually or semiannually to ensure that they're following their CMC section, just manufacturing, controls and something.
Q. Does the FDA track all manufacturers?
A. Yes.
Q. Can you explain that in a little more detail?
A. All legal manufacturers are required under the act to establishment register with FDA.
And once they're establishment registered that all the

drugs that are being manufactured through their site are listed with FDA, and the inspectors know what to look for when they go to those facilities to inspect.

Q. And you mentioned as part of the technical process there's also a section on labeling?

A. Yes.

Q. Starting with OTC drug, can you just walk us through the types of information that would be included on the label for an OTC drug?

A. So an OTC drug will have a list of the active ingredients, and generally the major inactive ingredients that may or may not be required depending on the dosage form. Most firms will put that on there anyway, and it will include the adequate directions for use.

So there will be a section that explains to you when you should use this drug, for what animals you should use it for, species, what age, what problems, and then there'll be any warning statements. Like, don't use on old animals or something like that just to prevent adverse events that are typical with that drug in older animals.

Q. And what type of information would be present on the label for a prescription drug?

A. So prescription drug have multiple sections that are required that includes that statement that we talked about, the federal law restricts this drug to use by or on the order of a

license veterinarian. It also includes an indication section that explains what the drug is used for. It will often have a section describing how the drug works.

There's actually a lot of information on a prescription drug label that isn't required an over-the-counter drug label.

So it will have that indication section, direction for use, how the drug works. It can vary how in depth that goes, but it's generally on there.

They'll be a section of warnings and contraindications so that the veterinarian knows which patients shouldn't prescribe that drug for, and then there will be an identifier of the manufacturer, the distributor with contact information and a description of any adverse events that are commonly seen with that drug so people know how to identify an adverse event and report it. Those get reported to the manufacturer or the FDA directly.

I'm sure there's other things that I'm forgetting. It also would have the statement of ingredients, including -- depending on the dosage form.

Injectable dosage forms are required to have a complete list of all the ingredients, including the concentration of each ingredient.

The oral formulation have to have the active ingredient, and then if there's any major inactive ingredient

that might cause an allergic reaction or something. Those would be listed.

Q. And would the information that you described that would appear on the label, would that be included with every bottle of a particular drug?

A. Yes.

Q. Can oral instructions replace that written label?

A. No.

Q. What, if any, records does the FDACVM maintain of approved animal drugs?

A. FDACVM maintains an internal database that's the Stars database where we track all the investigational and approved drugs, and that includes every supplement to any existing application and how that was handled, what happened with it. Sometimes drugs are sold at bought and sold commodities, so it might have a new firm that's in charge of that drug.

Q. And, Dr. Bowman, once a drug is approved by the FDA, can any company manufacture that drug?

A. No.

Q. Why not?

A. That drug is sponsored by a specific drug company and that drug company is the only one that can make it in accordance and has access to all the proprietary information that's in their application that explains how the drug has to be manufactured in order for it to be safe and effective.

Q. Can a manufacturer of an approved animal drug change the active ingredients without first going through the FDA?
A. No.
Q. How about the amount of a particular active ingredient in a drug, can a manufacturer change that without going through the FDA?
A. No.
Q. And does the FDACVM oversight end after a new animal drug is approved?
A. No. After a new animal drugs are approved, the firm continues to submit new annual reports that describe how much of the drug was manufactured, how much was sold into distribution.

They provide information on all the adverse events. And they do that more often than once a year if the adverse events qualify as significant adverse events, but definitely once a year even for the most minor reported adverse event, and they get regular inspections post-approval.
Q. What tools does the FDA have to enforce compliance with FDA regulations?
A. We have the -- generally with an approved drug, we will send a warning letter if something's wrong, and those firms have a lot of interest in coming into compliance. Often that's all that's required, but we also have the ability to do seizures or injunction.

We can enjoin a firm not to manufacture certain types of drugs anymore if they've proven that they can't manufacture them properly, or we can have a drug withdrawn from the market.

Q. You also mention that there may be criminal referrals; is that right?

A. Yes.

Q. What sort of employees work in that division of the FDACVM?

A. So we have an office, an FDA office of criminal investigations, and that's staffed by agents, similar to FBI agents, but they're tasked with following up on criminal referrals from all of FDA for different types of drugs.

Q. You also testified previously about adverse events, can you just explain what that means?

A. So adverse events are unexpected or unpleasant things that happen to you or your animal after a drug is administered. Sometimes they're not actually related to the drug.

But if the labeling is complete, it should give you an idea of what kinds of adverse events you might expect to find if you overdose the drug, or maybe the dog or the animal is dehydrated, and therefore it wind up with a higher blood level than you would have expected from the approved dose and therefore experience some adverse reaction.

Q. Why are those reported to the FDA?

A. That's a monitoring tool that we can use to ensure that the products are continuing to be safe and effective under

conditions of actual use, and that they're being manufactured properly.

Q. I'd like to shift to talk a little bit more about prescription drugs and over-the-counter drugs.

Can you just explain what the difference is and how someone would acquire a prescription drug versus an over-the-counter drug?

A. So an over-the-counter drug for animals would be purchased from a feed store or a pet store or maybe a tack store for horses, and it's just like when you go into the pharmacy and you buy Ibuprofen off the shelf. You just pick it up off the shelf. You walk to the counter and you can purchase it.

If you are purchasing a prescription animal drug, you would need a prescription or it would be dispensed directly to you. When your veterinarian treated your animal, he would dispense -- he or she would dispense that prescription animal drug at the time that they determined that that was the appropriate treatment for your animal.

Q. How does the FDA determine whether a drug should be sold as over-the-counter drug or as a prescription drug?

A. It goes back to that adequate directions for use. If adequate directions for use for the layperson can be written, the drug will be approved as an over-the-counter drug.

Certain things are considered to be red flags to adequate -- to the use by the laymen. That would include

things like IV administration, if the drug had to be given intravenously right into a vein, that's going to require that the drug be prescription animal drug.

And there are also drugs that have to be given by nasogastric tube that will require that the drug be a prescription animal drug.

If a diagnosis is required prior to determining that that is the drug of choice for that patient, then that would be a prescription drug because a veterinarian has to make that diagnosis and prescribe that drug.

Q. Dr. Bowman, what is a nasogastric tube?

A. A nasogastric tube is a tube that's inserted generally in horses, but could also be in dogs, through the nose and down into the stomach.

And if you do it improperly, you can wind up with it in the lungs. And then if you administer medication into the lung that was intended to the stomach, you can actually kill an animal.

Q. You also mentioned the term "layperson" or "laymen;" is that what you use to refer to someone who is not a veterinarian?

A. Yes.

Q. And you mentioned the term "IV" drug?

A. Yes.

Q. Does that stand for intravenous drug?

A. Yes, it does.
Q. And are those typically prescription?
A. Yes.
Q. Are you familiar with the term "IM" drug?
A. Yes.
Q. What does that mean?
A. That's an intramuscular injection.
Q. Are those drugs, IM drugs, typically over-the-counter or prescription?
A. They can be either depending on the species that they're for and the indications for use.
Q. And what if a drug description says it should be administered IV or IM?
A. Then it would have a prescription drug label.
Q. Are there oral animal drugs that require prescription?
A. Yes.
Q. Can you give me an example?
A. Phenylbutazone.
Q. That's the Bute that we talked about earlier?
A. Yes.
Q. So the method of administration is one factor, but it's not the only factor; is that fair to say?
A. Yes.
Q. Are you familiar with the concept of nutritional supplements for humans?

A. Yes.
Q. Does the FDACVM recognize that category for animals?
A. No.
Q. Can you explain?
A. When the law was written, it's called the DHSA, the Dietary Health Supplement Act, animal drugs or animal products were left out.

Our products are either foods or drugs or medical devices, but we don't have a category for dietary supplements.
Q. So it would be either considered a food or a drug?
A. Yes.
Q. Have you heard the term "homeopathic"?
A. Yes.
Q. Does the FDACVM recognize a separate category of drugs known as homeopathic drugs?
A. No.
Q. Are there any homeopathic drugs approved by the FDACVM?
A. They wouldn't say homeopathic on the label. They would just be drugs.
Q. I'd like to shift and ask you a little bit your experiences in veterinarian practice. I asked you earlier about the term "VCPR." Are you familiar with that term?
A. Yes.
Q. What does it stand for?
A. It stands for the veterinarian-client-patient relationship.

Q. And in that relationship who's the client?
A. The client is usually the animal's owner or a person designated by the animal's owner to act in its behalf.
Q. Who is the patient?
A. The patient is the animal.
Q. What's the concept of establishing a VCPR?
A. In order to provide good medical care, it's important that the veterinarian establish a relationship, examine the patient, meet the owner, come to an agreement that, you know, if I'm going to care for this patient, sort of implicit that the owner is going to provide the recommended care and the veterinarian will provide follow-up.
Q. And how would a veterinarian establish a valid VCPR with a new animal patient?
MR. FASULO: Objection.
THE COURT: Basis?
MR. FASULO: Vague.
THE COURT: Overruled.
A. That would generally require that the veterinarian see the patient in person, examine that patient, collect a history of the patient's past problems as well as any current ones, perhaps run some diagnostic tests if the patient's exhibiting or having a current medical problem, and all that would be incorporated into the medical record.
And then if the patient is experiencing a current

medical problem, the diagnosis would be made and treatments prescribed.

Q. And what steps typically occur before a veterinarian legitimately issues a prescription for a drug?

A. That process I just described would take place in advance of that.

Q. So is it fair to say the veterinarian has to know the animal?

A. Yes.

Q. Is that prescription process you described the same for both new and existing patients?

A. It depends. At times with an existing patient that has a chronic medical problem, it might be enough if the veterinarian's already established that veterinarian-client-patient relationship to have a discussion with the owner about what's going on, and it may be the type of problem that a veterinarian can expect is a recurrence of a past problem, therefore may need the same treatment.

Q. Why do veterinarians conduct a physical exam?

A. In order to diagnose most problems and to establish the underlying health of the animal.

But in order to diagnose post-problems, you have to do a physical exam, because there could be a lot of reasons; for example, why a horse limps on its left foot.

It's limping on its left front leg, but you don't know

why until you've done that physical examination and made a diagnosis.

Q. I'd like to ask you some hypothetical questions regarding the presence or absence of a VCPR under various scenarios.

So what if a veterinarian never physically examines the animal, but sells the client an injectable drug, would there be a valid VCPR?

A. No.

Q. Why not?

A. Because he hasn't examined that animal and determined what the underlying problem is that he's prescribing a medication for.

Q. What if a client describes symptoms to the veterinarian over the phone, but the veterinarian never conducts a physical examination, would that be sufficient to establish a VCPR?

A. No.

Q. Why not?

A. Because as we were just saying, there can be multiple reasons for similar symptoms. And until the veterinarian has established what the actual diagnosis is, it's really impossible to prescribe a treatment.

Q. And what if a client sends the veterinarian blood tests conducted of an animal, but there's still no physical examination, is there a valid VCPR?

A. No.

Q. Why not?
A. Because the blood tests have to be interpreted in light of the physical exam findings and history of the patient.
Q. What if a client ask a veterinarian for a prescription drug by name without referencing the animal and there's no physical examination?
A. No.
Q. What if all those things happened between a pet owner and a non-veterinarian, would there be a valid VCPR?
A. No.
Q. Have you heard of the term "companion animal"?
A. Yes.
Q. Can you give us some examples?
A. Companion animals are generally, at least in the CVM world, horses, dogs, cats and small pets, like guinea pigs, gerbils, hamsters.
Q. Are cattle considered companion animals?
A. No.
Q. What about sheep?
A. No.
Q. What about pigs?
A. No.
Q. Are veterinarian different from drug manufacturers?
A. Yes.
Q. In what ways?

A. Veterinarians are license to practice medicine and drug manufacturers are in the business of manufacturing and selling drugs.

Q. And are veterinarians exempt from the FDA's regulations regarding drug manufacturing?

A. No.

Q. I'd like to review a few exhibits with you, Dr. Bowman. These consist of intercepted calls that are already in evidence, and I'd like to ask you a few questions based on the substance of those intercepted calls.

Ms. Jung, if you could please display Government Exhibit 169AT and play Government Exhibit 169A. And if the jurors would like to follow along with their binders, they can turn to tab 169AT.

For the record, this is an April 30, 2019 call between Lisa Giannelli and Norman more forward.

If the jurors are ready, I ask Ms. Jung to please play Government Exhibit 169A.

(Media played)

(Media stopped)

BY MS. MORTAZAVI:

Q. Dr. Bowman, are you familiar with the term RX?

A. Yes.

Q. What does that refer to?

A. That refers to prescription drugs.

Q. Assuming there was no veterinarian participating in this call, was there a valid VCPR?

A. No.

MS. MORTAZAVI: Ms. Jung, could you please display Government Exhibit 182T and Government Exhibit 182.

And if the jurors would like to follow along in their binders, they could turn to that tab.

For the record, this is an April 27, 2019 call between Lisa Giannelli and Timothy Collins, and I'll have Ms. Jung please play Government Exhibit 182.

(Media played)

(Media stopped)

BY MS. MORTAZAVI:

Q. Dr. Bowman, in that call, were there any drugs described that would be considered prescription dugs?

A. Yes.

Q. Could you name some?

A. The Banamine, the Bute and the omeprazole.

Q. And again, assuming there was no veterinarian participating in that call, was that request a valid VCPR?

A. No, it wouldn't.

And let me clarify, omeprazole can be over-the-counter or prescription depending on the administration instructions.

Q. The Bute and Banamine would be considered prescription?

A. Yes, there's no over-the-counter version of either of those

drugs.

Q. Can you repeat your answer I'm not sure I caught it. Is this request a valid VCPR?

A. No.

Q. And why not?

A. Because there's no discussion of the -- there's no identification of the animal. There's no verification from a veterinarian that these drugs would be appropriate for dispensing to this client.

There's no discussion of the information that would be needed to add into a medical record.

MS. MORTAZAVI: Ms. Jung, you can take this down, and if you could please display Government Exhibit 185T and Government Exhibit 185.

And if the jurors would like to turn to that tab in their binders and they can follow along.

Ms. Jung, if you can please play Government Exhibit 185.

(Media played)

(Media stopped)

BY MS. MORTAZAVI:

Q. Dr. Bowman, does that reflect a valid VCPR?

A. No.

Q. Why not?

A. There's no identification of the animal that these

medications will be used on. There's no discussion of whether that would have approved the dispensing of medications or the problem that's being treated.

It sounds like it's just two people having a transaction.

Q. Dr. Bowman, you mentioned that in your role as FDACVM, I believe you mentioned you conduct reviews on safety and efficacy; is that correct?

A. In my old role I did, yes. .

Q. All right. Are those sometimes referred to as GRASE analyses?

A. Okay. I do GRASE analyses now, a little bit different than the review of safety and effectiveness data.

Q. Can you tell us what that term stands for, GRASE?

A. So a GRASE is a review of an unapproved drug where we're looking to determine whether it's generally recognized as safe and effective by experts in the area.

If it is generally recognized as safe and effective by experts in the field, then it would not require a new animal drug approval because it wouldn't be a new animal drug.

Q. What steps do you take when you undertake a GRASE review?

A. So when I do a GRASE review, I take all the information that we have about the drug to determine its intended use and I evaluate whether the drug is listed with FDA, if we know who the manufacturer is, whether the manufacturer is establishment

registered. I check to see if that drug is approved or an investigational drug that's being misused.

And I also then using that intended use information is evidence of intended use, I go through and I search the published medical literature, the peer review literature, to look and see what types of studies have been done to establish any level of safety or effectiveness for that drug for that use.

Q. As part of that process, do you check whether a drug is FDA approved?

A. Yes.

Q. Do you check whether the manufacturer is registered with the FDA?

A. Yes.

MS. MORTAZAVI: I'm going to read into the record a stipulation between the parties, your Honor.

This is Government Exhibit 9002, and I'm going to forego the initial paragraph.

THE COURT: Yes.

MS. MORTAZAVI: If called to testify at trial, representatives of the Food and Drug Administration Center for Veterinary Medicine, "FDA" would testify that (a) after conducting a diligent search of all relevant records in databases, the FDA has no records indicating that any of the following companies, entities or individuals were ever

registered with the FDA to manufacture drugs in the United States:

Equestology, Inc., Equestology LLC, Seth Fishman DVM, 21st Century Biochemicals, Inc., Jordan Fishman, Equiformance, Equi-Science, Equi-Tech, Specialized Performance Compound.

B. After conducting a diligent search of all relevant records and databases, the FDA has no records indicating that any of the following drug products were listed with the FDA:

VO2 Max, BB2, BB3, Serenity, TB-7, (Tymosyn Beta) ITPlus, BPB, HP Bleeder, HP Bleeder Plus, Homeopathic Bleeder Paste, EPM Double Kill, Iron Sucrose, GNRH, PSDS, (Pain Shot DS), ACTH.

And C. After conducting a diligent search of all relevant records and databases, the FDA has no records indicating that the FDA issued export certificates for any of the following companies, individuals, entities or drug products:

Equestology, Equestology, Inc., Equestology LLC, Seth Fishman DVM, 21st Century Biochemicals, Inc., Jordan Fishman, Equiformance, Equi-Science, Equi-Tech, Specialized Performance Compound, and I'll stop reading this and skip to the bottom.

It is further stipulated and agreed by and between the parties that this stipulation which is Government Exhibit 9002 may be received in evidence at trial, and the government offers Government Exhibit 9002.

THE COURT: It will be received. This is in evidence. It's an agreement between the parties, and this is evidence she may consider.

(Government's Exhibit 9002 received in evidence)

BY MS. MORTAZAVI:

Q. Dr. Bowman, were you asked to evaluate whether certain drugs received any approval from the FDACVM?

A. Yes.

Q. Were you also asked to conduct a GRASE review of various drugs?

A. Yes, I was.

Q. And who asked you to do that?

A. You do.

MS. MORTAZAVI: So I'd like to review some categories of drugs with you and then discuss the analysis that you conducted in this case.

Ms. Jung, could you please display for the jurors and the witness Government Exhibit 711 which is a record that was extracted from Lisa Giannelli's computer seized from her residence.

Q. Dr. Bowman, I'd like to review this document with you which consist of a list of different drugs.

Looking at the first category, HP Bleeder Plus.

Ms. Jung, if you could focus on it. That's perfect, thank you.

Can you please read this into the record, Dr. Bowman, starting with "a combination."

A. A combination of a proven.

MR. FASULO: Objection. The document speaks for itself.

THE COURT: I'll give her some latitude. She's not going to read the whole document. It is in evidence. The jury understands that.

MS. MORTAZAVI: Certainly not.

A. "A combination of a proven and test free "bleeding" (EIPH: Exercise induced pulmonary hemorrhage) and analgesic. The analgesic constituents have been published as effective and safe in a peer reviewed study in global and journals."

Q. Let me pause you right there.

Are you familiar with EIPH?

A. Yes.

Q. What is that?

A. It's exercise induced pulmonary hemorrhage, and it occurs in the lungs following extreme exercise in some horses.

Q. And the term "analgesic" as used here, are you familiar with that is?

A. Analgesic are pain relievers.

MS. MORTAZAVI: I'm going to read into the record a portion of this description.

"HP bleeder plus contains the strongest test free

vasodilators available on the market. Vasodilation is a benefit to all athletes shown in numerous published articles for humans. Horses benefit even more as they are prone to EIPH. Lasix is the current common treatment for EIPH which will aid in the reduction of blood volume, but will also produce dehydration and the risk to the equine of tying up and other conditions. HP Bleeder Plus can achieve same results without the side effects of Lasix."

Q. I'm going to ask you about some of the terms.

Are you familiar with vasodilators?

A. Yes.

Q. What are those?

A. When you think of a blood vessel, around the outside of that blood vessel, there's a layer of muscle. So vasodilator is a drug that relaxes that muscle and allows the blood vessel to expand and that just tends to reduce blood pressure.

Q. Are you familiar with Lasix?

A. Yes.

Q. What is that?

A. Lasix, is furosemide. It's a commonly used drug that causes the body to eliminate excess fluid and therefore reduces the blood volume and blood pressure.

Q. And to just distill it down, what claims are made here about this drug intended use as you understand it?

MR. FASULO: Objection.

THE COURT: Grounds?

MS. MORTAZAVI: It's her expert opinion.

MR. FASULO: The document speaks for itself.

THE COURT: Overruled.

Ms. Mortazavi is asking for your understanding.

A. Could you repeat the question.

Q. What is your understanding reviewing this product description about this drug's intended use?

A. So it appears that this drug is intended to use as a vasodilator in the treatment of horses with exercise induced pulmonary hemorrhage, and it claim to be better than the standard treatment which would be Lasix.

Q. Are those claims related to the effecting the structure or function of an animal?

A. Yes, and treating a disease.

Q. So is this a drug that would typically require a prescription?

A. Yes.

Q. Was HP Bleeder Plus FDA approved?

A. No.

Q. Were you asked to conduct a GRASE analysis?

A. Yes.

Q. And what were your conclusions?

A. My conclusions were that there are not any published articles to support that this drug is safe or effective for

intended use.

Q. Ms. Jung, could you please display Government Exhibit 1018.

Dr. Bowman, I'm going to ask you about this particular label. Does this contain all the information the FDA typically requires on an approved drug label?

A. No, it doesn't.

Q. What, if any, information is missing?

A. So this label is missing a lot of the label sections. Because it's an IV administration, it would be expected to be a prescription drug, so it's missing the prescription legend is what it's called.

The law restricts this drug to use by or on the order of a license veterinarian. It lacks the contact information for the firm that manufactured it or distributed it.

It lacks a complete ingredient statement and an indication statement.

It also lacks cautions, precautions and other information that would be necessary in order to know when to safely use the drug.

Q. Ms. Jung, could you please display Government Exhibit 1122, 1123 and 1124.

MS. MORTAZAVI: For the record, these are photographs that are already in evidence of drugs that were seized during a search of Christopher Oakes's barn.

Q. Dr. Bowman, do you want to take a minute and just look at

the different angles of this particular label, which for the record it appears to have the writing on it HP bleeder and then a plus sign.

Dr. Bowman, I'm going to ask you a minute whenever you're done reviewing, whether you can tell us what information, if any, is missing from these labels that FDA typically requires?

A. Similar to the other label it lacks the identification of the manufacturer or the distributor with contact information. It lacks the indication for use.

It lacks the complete ingredient statement and it lacks the information, such as cautions, precautions and warnings that would be necessary to use the drug safely.

Q. Ms. Jung, if you could take these down and please display Government Exhibit 1407, 1408, 1409 and 1410.

Which is again, for the record, in evidence as photographs of a bottle that was seized or a drug that was seized from the Golden Shoe Training Center.

And, Dr. Bowman, I'll be asking you the same question regarding these labels whenever you had a chance to review, you can begin to answer?

A. Similar to the HP bleeder plus label, this also lacks the information on the manufacturer or the distributor with the contact information.

It lacks information. It lacks the prescription

legend, an indication statement. The direction for use don't even -- which it didn't on any of the labels -- doesn't even tell you what species you're supposed to administer to, and it lacks all the information about caution, precaution and warning statements and a complete ingredient statement.

Q. Ms. Jung, if you can take these down and please display Government Exhibit 161AT, and please play Government Exhibit 161A.

And again the jurors can follow along with their binders if they'd like or they can follow the transcript on their screen.

For the record, this is an intercepted call dated April 22, 2019, between Lisa Giannelli and Brian Malone.

Ms. Jung, can you please play this exhibit.

(Media played)

(Media stopped)

BY MS. MORTAZAVI:

Q. Dr. Bowman, having reviewed that phone call and that transcript, assuming there's no veterinarian on that call, does that reflect a valid VCPR?

A. No, it didn't.

Q. Why not?

A. It doesn't identify the horses these drugs are going to be used for. There's no veterinarian providing the authority to dispense those drugs, not even a reference to the veterinarian

has to pay or anything and there's been no diagnosis that we know of.

Q. And, Dr. Bowman, I'm going to ask you to lean the microphone a little closer to your mouth just to make sure everyone can hear you.

Ms. Jung, if you could please go back to Government Exhibit 711.

Dr. Bowman, do you see at the bottom of the first page there's a number 2 with bleeding pills?

A. Yes.

Q. Could you review the sentences that follow starting with "Bleeder pills increase vascular integrity and help reduce inflammation," and you can just look up at me when you're done reading.

Dr. Bowman, what claims, if any, are made about bleeding pills intended use?

A. The claims made include vasodilation, analgesic and an antiinflammatory claim in that they describe it as being equivalent of getting a low dose corticosteroid steroid. corticosteroid are antiinflammatory, so I would say it makes all three of those claim.

Q. Is this a drug that would typically require a prescription?

A. Yes, because it requires a diagnosis of EIPH before you would decide to dispense this product.

Q. Ms. Jung, if we could go back to the full exhibit,

Government Exhibit 711, and go to number 3 on the list which is on page 2 and that's VO2 Max.

Dr. Bowman, could you read the first line that appears under the red text starting VO2 Max?

A. "VO2 Max: HP Bleeder plus with additional ingredients. Usually 10 mils 4-5 fors prior to race."

Q. If you can read the next sentence that follows and you can pause at the end of that sentence.

A. "All-natural Japanese amino acid-based product that has profound vasodilatory properties."

Q. Is there a recommendation as to dose that's provided in the second paragraph, in the second to last line of this description?

A. In the last paragraph there is a dose provided.

MS. MORTAZAVI: I'm going to read that out loud into the record.

"Dose is 10-20 mls intravenously for 1000 pound 450 kilograms."

Q. So what claims are made as to this drug's intended use, Dr. Bowman?

A. So this drug is also being claimed as useful for horses with exercise induced pulmonary hemorrhage and it's claiming that it provides vasodilation and it proves lactic acid accumulation.

Lactic acid accumulates when horses intensely

exercise. Muscles produce lactic acid and they become somewhat anaerobic in their physiology and lactic acid can build up, so they're claiming that this will also aid in that process.

Q. And are the claims here relating to effecting the structure or the function of an animal?

A. Yes, and controls symptoms of disease.

Q. Is this drug one that would typically require a prescription?

A. Yes.

Q. Was this drug FDA approved?

A. No.

Q. And were you asked to conduct a GRASE analysis of VO2 Max?

A. Yes, I was.

Q. What were your conclusion?

A. My conclusion was that I couldn't find any published studies to demonstrate that there was any safety or effectiveness of this product for the indications.

Q. Ms. Jung, if we could take down this exhibit and please display Government Exhibit 1028 which is also in evidence.

If we could focus on just one of the labels that appear here, for the record, on what appears to be a label sheet.

Dr. Bowman, looking at this label which has the writing on it V02 Max, could you tell us if this contains all the information that the FDA would typically require on a drug

label?
A. No, it doesn't.
Q. What, if any, information is missing?
A. It's missing the prescription legend. It's missing the identifier of the manufacturer or distributor with contact information.
It's missing the indication section, a proper ingredient statement and the caution, precautions that would be relative to the specific use of this drug.
Q. I'm sorry, Dr. Bowman, I may have missed it.
Did you already discuss whether or not this included manufacturer information?
A. Yes.
Q. Ms. Jung, if you could please display Government Exhibit 1114, 1115, 1116 and 1117.
And for the record, these are photographs taken during the search of Christopher Oakes's barn that have been admitted by stipulation.
Ms. Jung, if you can zoom in on 1117.
Dr. Bowman, just given this angle, are you able to read most of the text on this label?
A. Yes.
Q. Does this appear to be the same product with a slightly different label than the one we viewed before?
MR. FASULO: Objection.

THE COURT: Sustained.

Q. Dr. Bowman, is there any information on this label, just given the current view that is missing that the FDA would require?

A. Yes. Similar to other labels we've looked at, this one is missing the manufacturer, distributor contact information. It's missing an indication section. It's missing a complete ingredient statement. It's missing the prescription legend.

Q. Thank you, Dr. Bowman.

If we take down these exhibits, please, Ms. Jung. And could you please display for the jury Government Exhibit 127BT and prepared Government Exhibit 127B, which is a portion of a call intercepted on April 4th, 2019 between Seth Fishman and Nick Devita.

Once again, the jurors are welcome to follow along with their binders or on their screen.

Ms. Jung, if you could please play this government exhibit.

(Media played)

(Media stopped

MS. MORTAZAVI: Ms. Jung, if you can take down, this exhibit, and please return to Government Exhibit 711, and if you could turn to page 2 of that exhibit number 5 on the itemized list.

For the record, this is PSDS, natural analgesic-pain

killer.

BY MS. MORTAZAVI:

Q. Dr. Bowman, could you read the first lines that follow the portion that I just read.

A. "This product is based on the original Panacin formulation. It has 2.5 times more D-Phenylalanine then all other compounded and production versions."

Q. Are you familiar with D-Phenylalanine?

A. Yes.

Q. What is it?

A. It's an amino acid.

MS. MORTAZAVI: And continuing on this description, the sentence that follows.

"It is a mild anti-inflammatory compound and is a prominent component in wound healing. Intense exercise always involved an anaerobic component and thus results in significant reductions in ATP, an increase in muscle lactic acid, and an increase in tissue acidity."

Ms. Jung, if you can turn to the next page to the description that continues. I'm going to read out loud the text in bold.

Best used over two to three days prior to strenuous exercise. The typical dose is 5 mls and the last dose is usually administered four to six hours prior to strenuous exercise.

BY MS. MORTAZAVI:

Q. Dr. Bowman, are there any claims made here about this drug's intended use?

A. They make claims that this drug will help with muscle fatigue and the name itself implies pain relieving aspect to this drug cause.

MR. FASULO: Objection.

THE COURT: Grounds?

MR. FASULO: Speculation.

THE COURT: Overruled.

You can continue, Dr. Bowman.

A. It's a pain shot double shot PSDS, so that certainly -- we would expect from that name that the drug would be used as a pain reliever as well as to improve the muscle function during extreme exercise.

Q. So is this a drug that would typically require a prescription?

A. Yes.

Q. Was this drug FDA approved?

A. No.

Q. Were you asked to conduct a GRASE analysis of this drug?

A. Yes.

Q. And what were your conclusions?

A. I was not able to find any substantial evidence of safety effectiveness for this drug in the published literature.

Q. Ms. Jung, could you please display Government Exhibit 1027.

Dr. Bowman, I know that the text given the coloring is a little tricky to read, but could you tell us, does this label contain all the information the FDA typically requires on an approved drug label?

A. No, it doesn't.

Q. What, if any, information is missing?

A. Well, it's missing the information that would identify the distributor, the manufacturer with contact information for them.

It's missing the prescription legend. It's missing the section and the warnings and precautions for the safe use of the drug.

And I'm not sure if that's a complete ingredient statement, but because it's an injectable product, it should give -- and maybe it does give the concentration of the active ingredients, but I don't know if the inactive ingredients are, if there are any.

MS. MORTAZAVI: Ms. Jung, if you could take down this and please play Government Exhibit 171A, and display its corresponding transcript 171AT.

For the record, this is a May 1, 2019 between Lisa Giannelli and Tyler Bitager (ph).

Ms. Jung, if you could please play.

(Media played)

(Media stopped)

BY MS. MORTAZAVI:

Q. Dr. Bowman, reviewing that transcript and that call, assuming there's no veterinarian that was apart of that call, did that reflect a valid VCPR?

MR. FASULO: Objection.

A. No, it didn't.

THE COURT: Overruled.

Q. Why not?

A. There's no discussion of what horse this is for, whether he's trying to accomplish -- he says it's to calm them down, but for what purpose. That would make a difference into what drug you would prescribe.

If you're trying to calm them down to have their feet trim, you might use a different product, and it would depend on when its next race was, that type of information, and none of that is going on, so there's no evidence that there was a veterinarian in this conversation.

THE COURT: Ms. Mortazavi, when you get to a convenient breaking point.

MS. MORTAZAVI: Your Honor, I'm about to move onto a new category approach, so this might be a good breaking point.

THE COURT: All right.

Ladies and gentlemen, why don't you leave your notepads on your seat with the transcript binders. We'll take

a short break.

Please remember not to discuss the case during the break and wait until all evidence has come in before you start discussing the case with each other.

I'll see everyone back here in about 10 to 15 minutes.

All right. Thank you.

Dr. Bowman, you remain under oath, so please do not discuss your testimony with anyone during the break.

Thank you.

(Continued on next page)

(Jury not present)

THE COURT: Is there anything we need to discuss?

MS. MORTAZAVI: Not from the government.

MR. FASULO: Not from the defense.

THE COURT: Thank you, everyone. Have a good break. I'll see you back shortly.

(Recess)

THE COURT: Before we bring the jurors back, Mr. Fasulo, I just want to mention to you when you and your colleagues are shuffling papers and talking, sometimes it's a little loud and distracting.

MR. FASULO: We'll be very careful.

THE COURT: Try to be mind. Thank you.

(Continued on next page)

(Jury present)

THE COURT: Dr. Bowman, you remain under oath.

Ms. Mortazavi.

MS. MORTAZAVI: Thank you, Your Honor.

Ms. Jung, can we please display Government Exhibit 711, and please turn to page 3 and item number 7 on the itemized list.

BY MS. MORTAZAVI:

Q. I'm going to read this out loud for you, Dr. Bowman, in red text.

"GNRH Factrel, Androgenic Hormone

Gondorelin Acetate is similar Factrel and identical in sequence to Cystorelin. This product is best used for sulking horses, typically half to full bottle is used four to six hours prior to strenuous exercise."

Dr. Bowman, are you familiar with any of the terms that I just read out?

A. Yes.

Q. Could you tell us which ones and what they mean?

A. So Gondorelin acetate is the active ingredient in two -- at least two approved animal prescription drugs. Factrel and Cystorelin, those are the brand names of two approved products.

They talk about this drug being used for sulking horses. I think that's a term more commonly used in the horse industry as sour horses, so horses that are not willing to put

forth their best. They may be a little afraid of the other horses on the track, maybe they don't even want to leave the stall or the barn area. It sounds like this drug is being promoted for that use.

Q. Based on this description, what claims are made about this drug's intended use?

A. It's an androgenic hormone so that is a hormone that would increase the androgens which are the testosterone so that would increase the aggressive behavior of the horse.

Q. So are there claims made here relating to effecting the structure or function of an animal?

A. Yes.

Q. Is this a drug that would typically require a prescription?

A. Yes, it is.

Q. Is this drug FDA approved?

A. No, it's not, not this version of the drug. Factrel and Cystorelin are not approved.

Q. Were you asked to conduct a GRASE analysis of GNHR?

A. Yes, I was.

Q. What were your conclusion?

A. I couldn't find any published study from the literature to support the safety or effectiveness of Dr. Fishman's version of GNRH.

MS. MORTAZAVI: Ms. Jung, can you please display Government Exhibit 1023 and focus in on one of the label on

this with the name GNRH.

Q. Dr. Bowman, could you tell us looking at this if there is any information missing that the FDA would typically require?

A. Yes.

Q. Could you explain?

A. So this label is also missing the information on the distributor or the manufacturer with contact information. It's missing the prescription legend. The indication section, I assume that this was -- it's a powder for injection, so that probably is a complete list of the ingredients on this one, but it does lack warnings and precaution statement that would be necessary.

MS. MORTAZAVI: Ms. Jung, could you please display Government Exhibit 1404, 1405 and 1406.

For the record, these are photographs of a bottle that was seized from a search of the Golden Shoe training center. Could you focus in on Government Exhibit 1405 and 1406.

I'm going to read out loud the text that appears in bold at the top of this label, GNRH.

Ms. Jung, if you can take this down and please display Government Exhibit 1507, which for the record is another photograph of a bottle that was seized from a search of the barn of the Mount Hope Training Center.

And once again, I'm going to read the text that appears in bold at the top of the label, GNRH.

Ms. Jung you can take this down, and please display Government Exhibit 711. Once again, turn to page 3.

This time if you could focus on item number 8. ITTP Plus increase oxygen release in blood, and I'm going to be reading the description as a whole.

"ITPP plus other ingredients. ITPP increases oxygen release. Compared to what's sold online, it's less than half the price. Most people are using half bottle night before and remainder of bottle four to five hours before event."

BY MS. MORTAZAVI:

Q. Dr. Bowman, what claims are made here about this drug's intended use?

A. It appears this drug's intended use is to increase the oxygen content in blood, thereby improving performance by having a sufficient amount of oxygen for the muscles to work.

Q. Is that a claim that relates to the structure or function of the animal?

A. Yes, it is.

Q. Is this a drug that would typically require a prescription?

A. Yes, it is.

Q. Is this drug FDA approved?

A. No, it isn't.

Q. Were you asked to conduct a GRASE analysis of this drug?

A. I think it's the same drug. I did IT plus, but I would have found anything that was for ITPP plus in my searches if it

were there.
Q. And in your analysis of IT plus, what were your conclusions there?
A. My conclusion was that there is no evidence in the published literature to support the safety or effectiveness of this drug for any purpose in horses.
Q. Once again, Dr. Bowman, I'm going to ask you to pull the microphone closer.
Ms. Jung, if you could please display Government Exhibit 1025, focus on one of the labels on this label sheet.
Dr. Bowman, could you tell us what information is missing, if any, that the FDA would typically require?
A. So it's missing the distributor or manufacturer contact information, the indication section. It's missing the contraindications and warnings and the prescription legend.
And I will give the benefit of a doubt that that may be the complete ingredient statement; however identifying propriety amino acids and sugars would not be an acceptable ingredient definition.
Q. You stated "proprietary amino acids and sugars," is that the actual text that appears on this label?
A. Proprietary AA which stands for amino acids and sugars.
Q. Is it sufficient as part of an ingredient list to just include propriety blend or here, proprietary AAs?
A. No, it isn't.

Q. Why not?
A. You have to identify each active ingredients by its specific established name.
Q. Ms. Jung, if you could take down this exhibit and please display Government Exhibit 711, and this time turn to page 4.
Looking at number 9 on the itemized list, I'm going to read portions of this into the record, Dr. Bowman, but for the record, did you review this entire description as part of your preparation for your testimony today?
A. Yes, I did.
MS. MORTAZAVI: "TB-7 accelerated tissue repair especially in lungs. It has in some cases been effectively used as short-term prerace, but in most cases this has been short lived and with athletes crashing. Like all immunomodulators they are highly beneficial in small strategic doses and promote overall healing and increased immunity.
Q. Are there any claims made here about this drug's intended use?
A. Yes.
Q. What are those?
A. This drug has an intended use of promoting healing, and especially postrace, after postrace bleeding, so for horses with the EIPH.
Q. And are those claims that relate to the structure or function of the animal?

A. Yes, they do.
Q. Is this a drug that would typically require a prescription?
A. Yes.
Q. Is TB-7 FDA approved?
A. No, it isn't.
Q. Were you asked to conduct a GRASE analysis?
A. Yes, I was.
Q. What were your conclusions?
A. My conclusion was that there was no published medical literature to support the use of this compound in horses for this use.

MS. MORTAZAVI: Ms. Jung, could you please display Government Exhibit 1111, 1112 and 1113, which for the record are photographs of drugs that were seized from the barn of Christopher Oakes.

Q. Dr. Bowman, if you need a minute to review the three photographs, I'm going to be asking you, what, if any, information is missing from this label that the FDA typically requires.

I'll repeat my question, Dr. Bowman. What information, if any, is missing from this label that the FDA typically requires?
A. This label is missing the identifier for the manufacturer, the distributor with contact information. It's missing the prescription legend.

It's missing the indication section, and it's unclear whether that is intended to be a complete ingredient statement. But because it's an injectable product or it's intended for injection, it would be required to give the concentration of each active ingredient which it does not, and there's no warnings or precautions.

MS. MORTAZAVI: Ms. Jung, if you could please take down these exhibits. Could you please display Government Exhibit 320FK, and if you could focus on the messages in the middle starting with March 1, 2019, 2:31 p.m., and then the section that follows.

And for the record, this is a record of Equestology that is already in evidence per stipulation. I'm going to read it into the record.

"Lisa Ranger Cell. Some of the TB-7 I have here is expired. Is it still good. Expired May 2018.

Seth AA: Yes.

Lisa Ranger cell: Okay."

Q. Dr. Bowman, what's the FDA's position on selling expired drugs?

A. You would not be permitted to sell expired drugs. If you were an approved product, you could extend your expiration dating through supplemental data potentially if it did stay within its parameters of effectiveness, but you can't sell expired drugs.

MS. MORTAZAVI: Ms. Jung, if you could please take this down and return to Government Exhibit 711, and again turn to page 4, looking at number 13 on the numbered list which is,

"ACTH, in small dozens will act as natural anti-inflammatory, larger doses 2CC or more will act as a sedation.

With testing of corticosteroid, there are not many viable options left. ACTH causes the adrenal gland to release cortisol, the body's natural corticosteroid."

Q. Dr. Bowman in this description of ACTH that continues onto the following page.

Ms. Jung, if you can just please turn to the next page and focus on that.

Do you see here a recommendation as to dose, Dr. Bowman?

A. *Yes.*

(Continued on next page)

Q. The typical dose is 250 IUs four to six hours prior to strenuous exercise?
A. Yes.
Q. Could you tell us looking at this description, what claims are made about the intended use of ACTH?
A. So the claim for ACTH is that it will increase the endogenous, the body's own production and release of corticosteroids.
Q. And are those claims related to affecting the structure or function of an animal?
A. Yes.
Q. Is this one that would typically require a prescription?
A. Yes.
Q. And is ACTH FDA approved?
A. There are two FDA approved animal drugs that has ACTH as their active ingredient, but they may not be marketed at the current time. There's also an approved human ACTH drug that is available.
Q. Is there a version of ACTH that has been approved for any of the companies that we reviewed previously?
A. No.
MR. FASULO: Time frame, Judge.
THE COURT: Clarify, please.
Q. Dr. Bowman, when you review the FDA's database for approved drugs, for what time period does that database apply?

A. That database started in 1989, 1990. And before that, it was in the file database, which was rolled into the new database. So I'm not sure exactly how far back it goes, but I would say 1965.

Q. That database goes back as far back at least 1989?

A. Yes, I just can't recall. I did look up to see when the dial data started. I think it was 1965, but I can't recall a hundred percent for sure.

Q. Were you asked to conduct a grassy analysis of ACTH?

A. Yes, I was.

Q. What were your conclusions?

A. I couldn't find any published medical letter literature to support the use of ACTH, this ACTH product, or for this use.

MS. MORTAZAVI: Ms. Jung, could you please display Government Exhibit 1022? If you can focus on one of the labels on the label sheet?

Q. Once again, Dr. Bowman, what is missing on this label that the FDA typically requires?

A. So this label is missing the contact information and identifier for the manufacture, or the distributor, it's missing the indication, it's missing the prescription legend It is missing the contraindications and warnings.

Q. And, Dr. Bowman, do you see at the bottom of this label, this appears to be a website?

A. Yes.

Q. Is that sufficient to establish manufacturer contact information?

A. No, it isn't.

Q. Why not?

A. Because the regulation stipulates they have to provide contact information with a telephone number.

Q. All right.

A. Address and telephone number.

MS. MORTAZAVI: Ms. Jung, if could you take down these exhibits and display Government Exhibit 1400, 1401, 1402, and 1403.

And, for the record, these are photographs of drugs that were seized from the Golden Shoe Training Center. I want to read out loud the bold portion at the top of the label that appears visible on Government Exhibit 1402, ACTH. Ms. Jung if you can please take this down an display Government Exhibits 1508, 1509, 1510, and 1511, which are photographs of the drugs seized from the Mount Hope Training Center. And I'm going read again from the top portion of the label in all caps and bold, ACTH.

Ms. Jung, you can take down these exhibits.

Can you please return to Government Exhibit 711, Ms. Jung. And could you please turn to the last page of this exhibit?

THE COURT: Can you hold up for one second? I have--

an issue with my LiveNotes.

MS. MORTAZAVI: Certainly, your Honor.

THE COURT: I think it might be coming back now.

MS. MORTAZAVI: Okay. Thank you, your Honor.

THE COURT: Thank you.

Q. I'm going to read into the record portions of this description that appears on Government Exhibit 711, Dr. Bowman, Serenity sedation. It's anti-anxiety for the most part. Takes away stress without affecting performance. Typically 5 to 10 IV four to six hours before event.

And then at the bottom, L-theanine can cross the blood brain barrier and has many published studies demonstrating it can significantly reduce anxiety and stress. It was also shown to increase GABA and stimulates dopamine in the brain. More recent studies have shown it increases serotonin levels as well, having the ability to increase three key neurotransmitters, the end result is a destressed mind and muscle relaxation.

Are you familiar with any of the terms I just read out?

A. Yes.

Q. Could you explain which ones and what those terms mean?

A. So, anti-anxiety is pretty self explanatory. It means it reduces the nervousness of the animal prior to the race. These ingredients, L-theanine -- Suntheanine is a brand name for a

version of L theanine, and those are amino acids. GABA is a neuro transmitter in the brain. And when you increase GABA and stimulate dopamine, that gives a feeling of wellbeing to the patient and increase serotonin levels as well, you know, just create a relaxed, happy patient.

Q. So are those all claims made about this drug's intended use?

A. Yes.

Q. Generally to affect the mood of the patient?

A. Yes.

Q. And are those claims related to affecting the structure or function of an animal?

A. Yes.

Q. Is this a drug that would typically require a prescription?

A. Yes, it is.

Q. Is this drug FDA approved?

A. No, it is isn't.

Q. Were you asked to conduct a GRASE analysis of Serenity?

A. Yes, I was.

Q. What were your conclusions?

A. I was unable to find any data to support the claims made for Serenity, and I concluded that it was not generally recognized as safe and effective for the intended use.

MS. MORTAZAVI: Ms. Jung, can you please display Government Exhibit 391S? And, for the record, this is a

document produced by Equestology.

Q. And, Dr. Bowman, looking at that label, can you tell us what, if any, information is missing that the FDA typically requires on a label?

A. So it's missing the manufacturer or the distributor and the contact information, it's missing the indication section, the prescription legend, a complete ingredient statement identifying all the ingredients and the concentrations of them, and the warnings and precautions that might be necessary to use the drugs safely.

MS. MORTAZAVI: All right. Ms. Jung, if you can take down this exhibit. And can you please display Government Exhibit 319R?

For the record, another document produced by Equestology that I will read into the record.

From Lisa Ranger, sent Thursday, June 8, 2017, to Seth Fishman, subject Serenity/Equility. Can you write a short explanation about Serenity and how to use it? Thanks, Lisa.

If can you take that down, please.

Please display Government Exhibit 308, once more a record from Equestology. I'll read this into the record from Seth Fishman, sent June 8, 2017, to Lisa Ranger, RE Serenity/Equility. I can make a simple description if you want. It's an anti-anxiety, for the most part. Takes away stress without affecting performance. Typically 5 to 10 CC IV

four to six hours before event.

Ms. Jung, if you can take this down, and please display for the jurors Government Exhibit 165AT and prepare Government Exhibit 165A? Once again, the jurors can follow along from their screens or binders.

This is an April 25, 2019, call between Lisa Giannelli and Joshua Parker. If you can please play.

(Audio played)

MS. MORTAZAVI: Ms. Jung, you can take this exhibit down. And can you please display Government Exhibit 1220, which is in evidence? And, for the record, is a photograph of a bottle that was seized from Jorgde Navarro's residence.

Ms. Jung, if we can rotate the image so we can see the label, which says BB3?

Q. Dr. Bowman, were you asked to conduct a GRASE analysis of something called BB3?

A. Yes, I was.

Q. And did you first check to see whether BB3 is an FDA approved drug?

A. Yes, I did, and it isn't.

Q. And what were your conclusions after conducting your GRASE analysis?

A. I was unable to find any data or information in the medical literature to support the use of a drug called BB3.

Q. Looking at this label, I know it may appear obvious, could

you give us three examples of what is missing?

A. The indication section, the prescription legend, the directions for use, the manufacturer identifier, the ingredients list.

MS. MORTAZAVI: All right. Ms. Jung, if we could please take this down, and could you please display Government Exhibit 309, which is a record produced by Equestology. I'm going to read it into the record. Ms. Jung, if you can focus on the header information and the lower-in-chain e-mail?

Thank you. From Lisa Ranger, sent Friday, January 4, 2019, to Seth Fishman, subject simple terms. If you could focus on the header information, in the higher-in-chain e-mail?

From Seth Fishman sent Saturday, January 5, 2019, to Lisa Ranger, subject, RE simple terms. See below.

And, Ms. Jung if you can focus on the line that says BB3 in red and the text that follows?

BB3 long acting blood builder. Would only let trusted clients have this.

Ms. Jung, if can you take this down and display 319J which is, again, a record produced by Equestology.

I'm going to read the header information and lower-in-chain e-mail. From Lisa Ranger, sent Wednesday, January 2nd, 2019, to Seth Fishman and Mary Fox, subject item description needed. Can you please send a short description of

each item, please?

And focusing on the descriptions, I'll read item number 1.

B3. This is a blood builder that is used five to six days prior. Usually it takes two weeks to see results. The dosing is once every two weeks. I would really stay low key on this one.

Ms. Jung, can you please display Government Exhibit 113AT and play Government Exhibit 113A? For the record, this is a February 21, 2019, call between Seth Fishman and Jeff Gillis.

(Audio played)

Q. Dr. Bowman, you testified earlier about Epogen. Do you recall your testimony?

A. Yes.

Q. Is there an equine-approved version of Epogen?

A. No.

MS. MORTAZAVI: Ms. Jung, can you please display Government Exhibit 113BT and prepare Government Exhibit 113B?

And, for the record, this is a portion of the same call, a later portion of the same call that we just played, February 21, 2019, between Seth Fishman and Jeff Gillis.

Ms. Jung, if you can please play.

(Audio played)

MS. MORTAZAVI: Good. You can take this down. And

please display Government Exhibit 113CT and Government Exhibit 113C, which is another portion of that same call we listened to. February 21, 2019, between Seth Fishman and Jeff Gillis. If you can please play this portion of this call.

(Audio played)

MS. MORTAZAVI: Ms. Jung, if you can take down this exhibit.

If you can please display Government Exhibits 4016 and 4017, which are photographs taken during the search of the office associated with Seth Fishman in Florida. And if we could focus on the bottles that appear in the center of this exhibits, Ms. Jung? I'm going to read what appears to be the drug name which is listed here, EGH, equine growth hormone.

Q. Are you familiar, Dr. Bowman, with equine growth hormone as a general concept?

A. Yes.

Q. What is it?

A. It's a hormone that's produced naturally in the body that is responsible for enhancing the growth of tissues and repair of cells.

Q. All right. And looking at this label, does this contain all the information the FDA typically requires on an approved drug label?

A. No, it doesn't.

Q. What information is missing?

A. It's missing the distributor or manufacturer information with the contact information, it's missing the indication section, the prescription legend, the information on the warnings, precautions, and it must have other ingredients besides just the DHEA, which --

MR. FASULO: Objection. Speculation.

THE COURT: Lay a foundation.

Q. You stated earlier, Dr. Bowman, that you're familiar with the concept of equine growth hormone?

A. Yes.

Q. That's separate from this particular drug, correct?

A. Yes.

Q. All right. And how are you familiar with equine growth hormone?

A. Understanding the physiology of the body and how it works.

Q. What is DHEA?

A. It's a chemical name for a compound that is metabolized in the body to androgen.

Q. Can that alone stimulate equine growth hormone in an animal?

A. Not that I'm aware of.

Q. All right. Now, you were about to describe why you believe the ingredient list here is incomplete. Can you finish your answer?

MR. FASULO: Objection.

THE COURT: Overruled.

A. The reason I believe that the ingredient statement is incomplete is because I believe it would be a powder if -- for reconstitution for injection if it was pure equine growth hormone, or even pure DHEA, but instead it's a liquid. So unless it was -- it hasn't already been reconstituted because it has the complete top in place. So it has some kind of diluent in it.

Q. Thank you.

MR. FASULO: Objection. Move to strike.

THE COURT: Overruled.

Q. What is that, diluent?

A. That is a liquid that's used in the manufacturer of pharmacy products that are injectable liquids. It's what the active ingredients that are solids dissolve into.

Q. You used the term reconstitute. Can you explain what that means?

A. Well, if you noticed some of the other products, they came as a powder in an injection vial with the directions to add bacteriostatic water to that. That's reconstitution. So it has a longer shelf life if it's in the dry powdered form, and you add the liquid just before you're ready to use it.

MS. MORTAZAVI: Your Honor, no further questions.

THE COURT: Thank you. Mr. Fasulo.

MR. FASULO: Thank you, your Honor. One moment.

THE COURT: Sure.

MR. FASULO: If I may?

THE COURT: Please, yes. Thank you.

CROSS-EXAMINATION

BY MR. FASULO:

Q. Good afternoon, Dr. Bowman.

A. Good afternoon.

Q. You and I haven't met prior to today; is that correct?

A. I believe that's correct.

Q. You have met with the government a number of times, correct?

A. Correct.

Q. And you've consulted with the government, right?

A. Yes.

Q. And you've gone over your testimony with the government, correct?

A. Yes, in general.

Q. And they asked you about your background, your job?

A. Yes.

Q. They asked you to look at some products, correct?

A. Yes.

Q. They asked you what your testimony would be related to those products, correct?

A. Yes.

Q. And as you come here today, you come as an expert in the

field of -- in your experience with the FDA, and also in your role as a veterinarian; is that correct?

A. With limitations, yes.

Q. Well, as we've spoken.

As a vet, though, you had to first go and take an undergraduate degree?

A. Yes, I did.

Q. You received that undergraduate degree, and as part of the requirements to get into medical school -- which is the next step, correct?

A. Yes.

Q. You had to take certain science courses as well, correct?

A. Yes, I did.

Q. You were exposed to a number of science courses during undergraduate, correct?

A. Correct.

Q. You took many courses in chemistry, organic chemistry?

A. I took courses in those, yes.

Q. Applied sciences, right?

A. Yep.

Q. And then you entered into a rigorous program at your school?

A. Yes.

Q. One of the finer programs in the country?

A. Well, I don't know about that, but it's a good program.

Q. It's a good program. And the program included not only a very comprehensive course load, but a lot of field experience, correct?
A. Yes.
Q. And part of the comprehensive course load meant being familiar with all the -- well, being familiar with chemical properties of various drugs; is that fair to say?
A. To a certain extent, yes.
Q. And you would say that it was a very highly competitive program, correct?
A. Yes.
Q. And expectations were high, correct?
A. Yes.
Q. You needed focus, right?
A. Yes.
Q. And commitment?
A. Yes.
Q. And a lot of studies to get to where you are today, correct?
A. Yes.
Q. And that's not only to get through the program, and then there was licensing -- then there was an ongoing program after that to become a vet, correct, after you received your MD?
A. Well, DVM, but yes.
Q. There were even additional courses relating to animals and

the effect of drugs on animals and treating animals, et cetera?
A. That was all incorporated into the veterinary program.
Q. Right. And you took all those, you took many of those courses, correct?
A. Yes.
Q. You took enough of those courses that you were able to graduate and then be licensed as a vet, correct?
A. Correct.
Q. That's approximately how many years ago?
A. It was in 1989.
Q. Since 1989 you've been dealing with -- you have been in your industry, meaning in the role of a veterinarian or in the role of a veterinarian in the FDA, correct?
A. Correct.
Q. And even through that time period, from 1989 to present, you have had a lot of ongoing continuing education, correct?
A. Yes.
Q. Both mandated by the agency?
A. And voluntary, yes.
Q. And also voluntary, correct?
A. Yes.
Q. And in addition, your work itself has educated you on an ongoing basis, correct?
A. Yes.
Q. And in fact, working for the FDA things, rules,

regulations, new drugs come out, changes -- changes often and causes you to do additional research and get up to speed with whatever the new trends may be, correct?

A. There is an amount of that, yes.

Q. And you've done all that, correct?

A. I've tried.

Q. Right. And within the context of your job in the FDA, you are a component of that job, you said the scientific analysis or scientific expert in the area, correct?

MS. MORTAZAVI: Objection. Vague.

THE COURT: Are you able to answer, Dr. Bowman?

A. We're called subject matter experts.

Q. Subject matter experts, correct? And that's in -- you're part of a whole group of people that you work with, correct?

A. Yes.

Q. Some are subject matter experts, right?

A. Yes.

Q. Then there are legal experts, correct?

A. Yes.

Q. And then there are investigatory experts, field experts?

A. Yes.

Q. And other titles for other people that work with you in your area, correct?

A. Yes.

Q. And you all work in this enforcement area, correct, that

you talked about earlier?
A. Maybe not all of us, but most of us, that you just described.
Q. There's a lot of cross -- sharing of cross information back and forth from different departments within the FDA when you're doing analysis, correct?
A. Depends on what kind of analysis you're referring to, not when we're doing the GRASE analysis. That is -- that's kind of all me. If I'm doing it, I don't consult with others.
Q. But there are specialists in regulatory language and regulatory interpretation, correct, within the agency?
A. Not that I know of, I guess, except for our lawyers.
Q. Your lawyers, for example, correct?
A. But they don't review my work.
Q. No, but they help to give direction as to how to interpret certain areas of the regulations; is that right?
MS. MORTAZAVI: Objection. Vague. To whom?
THE COURT: She can answer generally.
A. Sometimes.
Q. And on many -- on some occasions, you need to consult them, correct?
A. On some occasions they need to consult with us.
Q. That's true. The point is that it is a very complex system that's run at the FDA. Very organized and very complex, correct?

A. I don't think it's that complex. But, I mean, it does take a variety of scientific experts to get to the best answers.
Q. Right. And there's a variety of different divisions within the FDA, correct?
A. Yes.
Q. And everybody is working together to make sure that the rules are followed in the way that they are intended to be, correct?
A. That's the ideal.
Q. And you talked about one of the things you do is you notice companies, individuals, product manufacturers, of defects that may exist in the way they are interpreting the rules, correct?
A. Sometimes.
Q. Right. And sometimes a warning letter is sent, for example?
A. Yes.
Q. And in those letters, you try to resolve issues regarding labeling or regarding product usage or intended uses just like you talked about here today, correct?
A. And marketing, yes.
Q. And marketing, correct?

And some of those are informal procedures, right?

A. I think everything we described was pretty formal.
Q. Are there informal procedures as well?
A. I think the field staff may at times informally stop by a

facility and say, hey, you may not want to do that, but we're not part of that -- part of the process.

Q. And then there's a more formal process you're involved in, correct?

A. Correct.

Q. You talked about the different levels of that process, correct?

A. Yes.

Q. And it's your hope that you can resolve most of these with whoever it is that may be either misinterpreting or just violating a condition of the FDA or provision of the FDA regulations?

A. Correct.

Q. Is that fair to say?

A. That's fair to say.

Q. And during the -- during the course of this investigation, you spoke about a number of categories of product that you -- that the FDA oversees, correct?

A. Yes.

Q. And one of it was the idea of an approved drug, correct?

A. Correct.

Q. And that would mean, if I'm -- if I'm right, that would mean that the FDA has evaluated it, and it is now on an approved list as indicated through the FDA, correct?

A. Not exactly. An approved drug has -- is sponsored by a

single company. It doesn't just land on a list for anyone to use. It's a very specific proprietary product owned by a specific company.

Q. And they have that ownership for a number of years before it becomes a generic drug; is that right?

A. Yes. Generics are a different issue. It depends on the drug when the original pioneer drug is approved. It is usually eligible for five to seven years of exclusivity, but even once it's eligible for a generic copy, that is still an approval process virtually the same as the original approval process with a few shortened sections.

Q. And we talked about the approval process, that it's a comprehensive process. Would that be fair to say?

A. Yes.

Q. That covers, I think you said, seven areas, correct.

A. Correct.

Q. Each area, there has to be submissions as to support, the viability of the drug and, matching the criteria with each of those seven areas; is that fair to say?

A. Yes, it is.

Q. That takes -- and within each of those areas, part of it is testing of the drug, correct?

A. Yes.

Q. There's clinical tests that are done on various drugs, correct?

A. Yes.
Q. And those are done by the manufacturers or by the founders or veterinarians that are helping to create the product?
A. Or the people they employ to do that testing.
Q. Right. And those tests then have to be submitted to the FDA before, in fact, the drug could ever be approved, right, and the results of those tests?
A. Yes.
Q. Let me rephrase.

As well as the results of those tests?
A. Yes.
Q. And you stated that it could run a few years or up to 10 years; is that fair to say?
A. That's fair to say. I mean it can be shorter or longer. If it's a generic, it could be. Very short.
Q. After that process, the drug would be approved in the terminology that you just stated, correct?
A. I'm not saying it's absolutely necessary benchmarks for approval.

(Pause)

MR. FASULO: Let me just withdraw the last question. And, judge, I ask to strike the last answer. I'll ask another question because I don't remember the wording of the question.

Would it be fair to say that after the drug went through the process, it would either be approved or it would be

sent back for further testing or disapproved; is that fair to say?
A. We don't have a formal disapproval process, but it would either be approved or it would not.
Q. So, those are approved drugs, right? There's other categories of drugs that you look at. And when we say drugs, that's any product as used as you previously testified, correct?
A. Under the definition in the Federal Food and Cosmetic Act.
Q. Correct. And the second area is unapproved drugs, correct?
A. Well, as you alluded to, there's multiple areas, there's index listed drugs, there's conditionally approved drugs, there's generic approved drugs, there's pioneer approved drugs, and there are unapproved drugs.
Q. So there are all those areas that a drug could be sold but have those kind of -- those kind of labels put on it, correct?
A. I don't understand the question.
Q. You just named a bunch of areas where drugs would be considered approved under different labels, correct? Can you repeat that for us again?
A. That's not what I was talking about.
Q. But I'm asking you, under approved drugs can you give me the labels that would go with the approved drugs?
MS. MORTAZAVI: Objection. Vague.
THE COURT: Sustained.

Q. What did you mean by approved drugs.
A. When I refer to an approved drug, I mean a drug that is either an FDA approved pioneer drug, an FDA approved generic drug, or an FDA approved -- conditionally approved drug which is also in the process of getting its full approval.
Q. Other than those three categories of approved drugs, as you just stated, there's another level of drugs, which are unapproved drugs; is that fair to say?
A. That is fair to say.
Q. Can you define unapproved drugs as it relates to your role in the FDA?
A. Unapproved drugs are marketed animal drugs that lack FDA approval.
Q. Right. And would it be fair to say that within a vet's practice, a vet has the authority to prescribe both an approved drug as you stated and an unapproved drug?
A. A veterinarian under 21CFR530 should be prescribing an approved drug as long as there is one, an approved human or animal drug, that will work for the indication and the intended use. If there is no approved drug, then there are conditions under which it is possible to have drugs compounded, and those conditions are all laid out in 21CFR530.
Q. Correct. And if a veterinarian does not find an approved drug and has to compound a drug, it's within his discretion as a vet with his license to decide whether or not he believes

that drug is appropriate; is that fair to say?
A. He has to meet the conditions listed in 21CFR530, which include, among many other provisions, that the drug needs to be necessary to prevent death or suffering, and that there's no approved drug that can perform that function.
Q. And when you say prevents suffering, that's within the discretion of the veterinarian who is prescribing that drug, would that be fair to say?
A. Not entirely. I think there's a pretty good working definition of what is meant by animal suffering. I think -- I won't say that.
Q. Okay. But the FDA doesn't regulate that term of art; isn't that fair to say? That is done by a state-by-state basis under the licensing provisions of each state as it relates to veterinarians?
A. That law is a federal law, so that would be interpreted and enforced by federal enforcement.
Q. What is -- what is your understanding of the definition -- your legal understanding of the definition of suffering -- of an animal suffering?
A. Well, I'm not a lawyer, but I know when an animal is suffering when it's unable to eat, it's in pain, especially chronic pain. Those are the kinds of things that we look for. There's behavioral markers for all of those that are well documented in the literature so you can document when an animal

is in pain, which is not always easy because it's not like they can tell us.

Q. And it's the job of the vet to make that determination; is that fair to say?

A. Within a valid veterinarian-client-patient relationship after performing a physical examination of the patient.

Q. And that also the veterinarian-client-patient relationship is also a regulation that the veterinarian has to follow; is that fair to say?

A. Yes, it is.

Q. And it's a regulation that's not only set out in the language of the FDA, but is regulated by state-by-state statute, correct?

A. It is in both places.

Q. Right. And each state has a different way of interpreting what actually is expected in the veterinarian-client-patient relationship; is that fair to say?

A. I think it's fair to say that most of them mirror what the AVM, the American Veterinarian Medical Association definition is, which is very close also to what the federal definition is.

Q. But it's up to the state to make that determination as it regulates the veterinaries -- the vets that are licensed within their individual states; is that fair to say?

A. Unless it comes up in a federal violation, in which case it becomes a federal concern.

Q. Correct.

THE COURT: So I want to instruct the jury. Mr. Fasulo, you have a habit of saying "correct." I'm going to instruct you on the law. The fact that Mr. Fasulo says correct doesn't mean it's correct. All right?

Thank you.

MR. FASULO: Thank you, Judge.

I lost my train of thought for a second.

Q. You talk about 21CFR530, correct?

A. Yes, I do.

Q. And when you speak of 21CFR530, that is a section of the law that allows vets to compound certain drugs.

A. It allows veterinarians to compound drugs from approved human and animal drugs under the specific conditions laid out in 21CFR530.

Q. And that provision is specifically designated to instruct the vets as to what they can and cannot do?

A. That's one of the purposes.

Q. That is the purpose, correct?

A. That is one of the purposes.

Q. And it is the vet who is responsible for his own action --

MS. MORTAZAVI: Objection. Vague.

Q. -- as it relates to compounding?

If a vet decides to compound a product, it's the vet who's responsible for the actions of compounding that product?

A. I would need more information to answer that.
Q. Well, in compounding a drug under 21CFR530, a vet, hypothetically, can get two approved products and decide to use them together in a new product that's not available and use it on a case-by-case basis; would that be fair to say?
A. No.
Q. Well, tell me what compounding means to you, then.
A. When you're compounding under 21CFR530, if you're, it's a -- typically -- I'll use your example of the two different approved drugs.

If the two different approved drugs are available for your use and you want to use them together, you don't need to compound anything. You can just administer both drugs in accordance with their label and instructions. So compounding typically takes place more in the situation of animals come in a range of sizes, from a canary up to a hippopotamus, and the dosage forms that are approved typically don't come in a range that's suitable of all those weights and of all those animals.

Under the off-label use provisions, you can use a product that's an -- approved and intended for use in cattle for the canary, but the dosage form would be too concentrated, so it might be a fairly simple matter to dilute that to a concentration where you can dose the canary without killing it.

So those are the kinds of compounding activities. That's just one example of that would be allowed under

21CFR530.

Q. You talked about off label. Can you describe what that means?

A. So off-label use of an approved drug is any use that is different from the approved uses.

So the label says give 10 milligrams five times a day to a dog, and you have a cat with an issue you think would benefit from the active ingredient that's in this product but there's no approved cat drug, then you might choose to use that dog drug at the dose that's appropriate for a cat.

Q. When you say you might choose, who's the "you" that you're speaking about?

A. In that case, it would be the veterinarian making that decision.

Q. Okay. And the veterinarian would call upon their expertise and their experience in making that decision; is that fair to say?

A. They should look at references because we don't treat canaries, most of us, every day, so we would have to look that up and do some research before we made that kind of decision.

Q. Or use their experience if they are experienced in dealing with certain animals and the using of certain drugs; is that fair to say?

A. There should be a basis for that experience.

Q. Right. If they have a basis for it, they can use that

basis?
A. And that basis --
Q. Let me finish the question.
If they have that basis and the basis is something they can use to render that judgment of using that drug in that off-market way?
A. That would depend on what the basis is.
Q. All right. And when we're talking about basis, that would be the basis of the licensed vet, right?
A. No. The basis for the decision-making would have to come from someplace besides just a whim. So there would have to be some basis on which to have an expectation that that off-label use of the drug would actually be effective and safe for the condition that you've diagnosed after you've examined the patient and taken it history and done your diagnostics. There has to be a kind of sequential basis for the determination of the final treatment.
Q. That basis would be part of what the experience of that vet would be with the particular animals, with the particular drug, and with their particular research that they would do in regard to the prescription of that off-market drug; is that fair to say?
A. That sounds like a summary of what I just said. I think that's fair enough.
Q. Okay. Now, you talked about over-the-counter versus

prescription drugs. Do you remember your testimony regarding that?
A. Yes.
Q. And when you talk about over-the-counter drugs, those drugs would be readily available to the public without prescription?
A. Correct.
Q. And those drugs, would be available through various outlets; is that fair to say?
A. Yes.
Q. Through the manufacturers?
A. Not typically. But --
Q. Through feed stores?
THE COURT: Hold on. You're stepping on each other.
A. Typically, they'd be available through feed stores, tack stores, pet stores.
Q. Or through the vets?
A. Maybe on rare occasions. Most vets don't have the time or the money to invest in over-the-counter medications people can buy at the drugstore.
Q. But there's nothing that prohibits a vet from providing over-the-counter -- over-the-counter drugs to his clients; is that fair to say?
A. That is fair to say.
Q. And as far prescription drugs, are you familiar with the term herd management.

A. Yes.
Q. Can you describe to us what herd management is?
A. There are some situations -- for example, feed lots, and poultry farms -- where you're managing a group of animals in a closed setting as opposed to an individual animal.
Q. Are you aware of any setting where horses can be considered herd animals?
A. No.
Q. None?
A. Not within the confines of the drug world.
Q. So is it your testimony here today that any prescription to any horse requires the doctor to actually see that horse?
A. At some -- it may be not that day, but have had prior knowledge of that horse, have -- establish that veterinarian-client-patient relationship, yes.
Q. And when you say once a horse, who's the client, is -- the patient, once the horse is the patient, it becomes an existing patient; is that fair to say?
A. With limitations.
Q. As you know as a vet, would that be considered an existing patient if you were out there --
A. If I hadn't seen that patient for an extended period of time or the problem that I was being asked about was a new problem or didn't fall into the expectations of whatever old problems the horse had been treated for, then it would be a new

problem. And it could be a new patient, if it's been more than six months to a year, I would consider that a new patient again.

Q. But an existing patient could have the same problem for a number of years, but you're familiar with as the veterinarian, and you deal with that problem as an existing patient if you were a vet, correct?

A. I would --

Q. Let me rephrase.

A. Not over years.

Q. I'm going to withdraw that and rephrase the question.

THE COURT: I'm going to remind both out of, Dr. Bowman, you keep answering before Mr. Fasulo, and sometimes Mr. Fasulo, you're stepping on the answers. So both of you take a breath and let each other finish.

Thank you. Go ahead, Mr. Fasulo.

Q. There's a difference between new patient and existing patient?

A. Yes.

Q. You would agree that existing patient is a patient the vet had a relationship with, correct, prior to?

A. There's a time element in that. If the time element is not there, if you have not had an existing, ongoing relationship with that patient within a reasonable amount of time -- and there may be slight differences in different practice acts; we

haven't specified it that I'm aware of, in the federal law, but I know for most doctors' offices, it's a year. If you haven't been to see them in a year, you are considered a new patient again.

Q. And that's your understanding of most practices, correct? Is that what you're saying?

A. I think that would be a reasonable way to approach it for a practice.

Q. Is that also fair to say that is within the vet's discretion under his own license to make that determination?

A. No, I don't think it is. I think it's under the discretion of the practice acts for the states he's licensed in.

Q. So it's under the practice acts, and the vets consult the practice acts and then interpret what that practice act means in relationship to existing patients, and it's within their discretion to make the right judgment as to the art of those words?

A. Well, it's not just about the existing patient, it's about the existing problem.

Q. I'm only asking about existing patient.

A. Well, you can't just separate those. The existing patient --

MR. FASULO: Excuse me. Judge, she if can't answer --

MS. MORTAZAVI: She's trying to answer. She's telling you she doesn't believe you can answer it in isolation.

MR. FASULO: That's fine.

Q. So let me ask you: Would you agree the state regulations regulate what an existing patient relationship is?

THE COURT: That's a yes or no.

A. I think it depend on the state, not all states probably do.

Q. Would they give guidance as to what -- do you, as an expert here today, do you believe that the state statutes give guidance to the vets as to what an existing relationship is?

A. Most probably do.

Q. And therefore, would it be fair to say that you're not familiar with each of those state regulations?

A. Specifically regarding when a patient is a new patient versus an existing patient? No, I am not familiar with all 50 states and how they do that.

Q. You would agree it's up to the vet in his capacity as a licensed veterinarian in that state to consult the state statutes?

A. It is. And it's important to note that the veterinarian needs to be licensed in every state in which they are practicing medicine. So every state in which they are dispensing drugs as part of their practice, they need to be licensed in that state.

Q. And when you say dispensing drugs, they need to be licensed in the states where the patient is actually located; would that be fair to say?

A. And the state in which they have their facility.
Q. Right. So if my facility is in Delaware, I need to be licensed in Delaware if I'm working out of a Delaware location?
A. But if your patients --
Q. My question is if I'm working at a Delaware location, do I need to be licensed in Delaware if my office is in Delaware? Yes or no.
THE COURT: No. No. She can finish her answer. Dr. Bowman, you can answer.
A. Okay. So you need to be licensed in the states in which the animals are being treated. So you might live in Delaware, your facility might be in Delaware, but you may be treating patients in Maryland, Pennsylvania, and New Jersey, in which case you need to be licensed in all of those states.
Q. Which is my next question.
You also need to be licensed in the states where the animals are actually being treated?
A. If you're treating them, yes, of course.
Q. But you don't need to be licensed in the states where the owners are located?
A. Not necessarily. Unless the owners are located in the same states as the horses.
Q. Right. So it's possible -- you do not need to be licensed in a state in which an owner exists if that's not where the horse is actually being treated?

A. Well, if you're actually treating the horse, wouldn't you dispense the medications while you were there?

THE COURT: Dr. Bowman, you just need to answer the question.

THE WITNESS: I don't understand that question.

Q. If I own a horse -- hypothetically, someone owns a horse and they live in New York, and the horse is located in Kentucky and the horse is treated in Kentucky, if the vet is treating the horse that's located in Kentucky, the vet must be admitted as a licensed vet in the state of Kentucky?

A. Correct.

Q. He does not need to be admitted in the State of New York?

A. Correct.

Q. Thank you.

MR. FASULO: Judge, I don't know what time you want to break.

THE COURT: 1:00 o'clock. Unless you know that's --

MR. FASULO: That's fine. I just wanted to have an idea of where I should go next based on that.

Q. Now, during your direct examination you talked about typically -- it's typically a prescription, do you remember using that term of art?

A. No, I don't. Can you give me context?

Q. For example, you said IV medications are typically prescribed medications. Do you remember testifying to that?

A. That sounds right.
Q. When you use the term "typically prescribed," what did you mean by that term?
A. I meant that in the modern era, all the drugs that are administered by IV injection will be prescription drugs. I'm sure that you can find a couple of old, old products that are still marketed that may be marketed with IV on the label that are not -- do not bear the prescription legend and are not approved.
Q. And once again, when you say not approved, does that mean the drug cannot be dispensed?
A. In the case of the drug that I'm thinking of, I think if we did a GRASE evaluation, we would find that that drug is generally recognized as safe and effective under the conditions of use on its label, which would mean it's not a new animal drug, it's just an animal drug, and it can continue to be marketed.
MR. FASULO: Judge, that was a yes-or-no. Your Honor, can I have the last question read back, please?
THE COURT: No. I think that's how she can answer it, Mr. Fasulo.
Q. You used the term "not approved" again. Yes?
A. I don't know. You can read the answer back, and I'll tell you.
Q. When you use the -- I'll withdraw that question.

When you use the term "not approved," does that mean the drug cannot be dispensed? Yes or no.

A. It depends.

Q. Would that be yes or no?

THE COURT: No, no. It depends means she can't answer yes or no.

Q. Well, let me ask you this: If a drug was not approved, would that drug not be permitted to be dispensed?

A. If a drug is not approved but is marketed illegally, it is being dispensed but that doesn't make it legal.

Q. You talked about nutritional supplements for horses. You indicated that there are no regulations regarding nutritional supplements in the current FDA regulations.

A. For nutritional supplements, correct.

Q. And you talked about homeopathic drugs.

A. Yes.

Q. And you said that there isn't a separate categorization for homeopathic drugs.

A. Homeopathic animal drugs.

Q. Is that right?

A. That is right. There is no special category.

Q. Would it be fair to say that without any other information, it's hard to determine whether a nutritional supplement or a homeopathic drug would be considered an over-the-counter drug or a prescribed drug?

MS. MORTAZAVI: Objection.

THE COURT: No. She can answer.

A. If you're able -- repeat that question.

MR. FASULO: Can I have it read back, please?

THE COURT: Yes. Would the court reporter please read it back?

(Record read)

MS. MORTAZAVI: Your Honor, I renew my objection on the basis of the witness' last answer.

THE COURT: Overruled.

A. So a nutritional supplement is either a food or drug. It's not a special category where it has qualities of both. Nutritional supplements are oral. They have nutritional components in them that provide taste, aroma, nutrition. So that's -- if they make drug claims for animals, then they're going to be regulated as an animal drug. If they make structure function claims and they have elements of nutritional benefit to the animal and sufficient quantity to provide actual nutrition and they are administered orally, then they could be considered a food with the structure function claim.

As far as knowing whether a drug should be marketed prescription or over-the-counter, by looking at the label, we can -- I can't think of a single example where we couldn't tell that. Because if it's going to be suitable for over-the-counter administration, it has to provide adequate

directions for use by the laymen.
Q. And that is what you've studied, and that is what you've done for a number of years to make those determinations in the FDA, correct?
A. That's part of what I do.
Q. All right. And it requires a certain expertise to do that; would that be fair to say?
A. It requires a knowledge of regulations.
Q. And is there an expertise in the area of science in order to do and make those determinations; is that fair to say?
A. It's really not challenging.
Q. Do the people that work with you have similar backgrounds to you in terms of expertise and experience?
A. Not all of them, no.
Q. Do they have a scientific background?
A. Some of them do.
Q. Do they have a background that has experience in the area of labeling as it relates to medications.
A. In our compliance area, very few people actually have that experience.
Q. I'm asking about your area specifically.
A. Well, I'm in the division of drug compliance now, so one team of our division has that kind of subject matter expertise, the other teams do not.
Q. That's what I'm saying. You need to have a subject matter

expertise to contribute in that division in the way that you operate and the job that you do; is that fair to say?
A. We have guidance documents that very clearly and easily provide a chart so that you can look at a drug label and tell what it needs.
Q. And in order to do that, you have to receive certain training from the FDA as to how to use those charts and what value those charts have in the analysis that are being done?
A. No. Those guidance documents are available publicly. If you Google it, they'll pop right up. And they are written to the level, I think, of a 7th grade education, so that you can very simply and easily tell what needs to be on the label for each type of drug and how to tell what each type of drug is.
Q. And would it be fair to say there's a number of drugs that are not properly labeled that you have looked at during the course of your employment, right?
A. Yes.
Q. And a number of those drugs are manufactured by major manufacturing companies that are approved?
A. No.
Q. None of them, never?
A. No.
Q. Okay. And in terms of the ingredients that be listed, you have dealt with the issue of what ingredients need to be on the label and what don't, right?

A. Yes.
Q. And your division sends out a number of warning labels every year -- warning letters. I'm sorry. Every year.
A. We do.
Q. And some of those letters are sent to companies that have a history of doing the right thing all the time, and some are sent to companies that don't have that same history; would that be fair to say?
MS. MORTAZAVI: Objection. Vague.
THE COURT: Overruled.
A. They are sent to all kinds of companies.
Q. Right. And at times, a company makes a judgment error and needs to correct a label or needs to correct an ingredient list in order to comply with your regulations?
A. Yes.
Q. And at times, they do that and then they are in full compliance?
A. Yes.
THE COURT: All right. Mr. Fasulo, where is a good break point? If you're on a topic, you can finish. That's fine.
MR. FASULO: You know, Judge. This is a good point, and I can go on to the transcripts.
THE COURT: That's fine, then.
All right. Ladies and gentlemen, let's take our lunch

break. If we can be back in 45 minutes, that would be great. Please leave your notepads and the binders on the chairs, and do not discuss the substance of the case.

Dr. Bowman, please wait. Please be seated.

THE WITNESS: Oh, I was just standing.

THE COURT: Please do not discuss the case, the testimony, or anything related to the subject matters during your break. All right? Thank you very much.

(Jury not present)

THE COURT: All right. Please be seated, everyone.

Dr. Bowman, you remain under oath. I hope you have a pleasant lunch break, and we'll see you back after the break.

Okay. You may step down. Thank you.

THE WITNESS: Thank you.

THE COURT: Some of our jurors are exiting, so it's not appropriate for you to leave yet, Dr. Bowman.

Okay.

(Witness steps down)

THE COURT: All right. Is there anything we need to talk about?

MS. MORTAZAVI: Not from the government.

MR. FASULO: Not from the defense.

THE COURT: Okay. Great. Have a good lunch. I'll see you at about 1:45.

(Luncheon recess)

AFTERNOON SESSION

1:50 p.m.

(Trial resumed; jury not present)

THE COURT: Good afternoon, everybody. Please be seated.

Is our jury ready?

DEPUTY CLERK: Yes, your Honor.

THE COURT: All right. Will someone retrieve Dr. Bowman while we're getting seated?

(Jury present)

THE COURT: Good afternoon, Dr. Bowman.

THE WITNESS: Good afternoon.

All right. I hope you had a pleasant break and that our jurors did as well.

Mr. Fasulo, whenever you're ready.

MR. FASULO: If I may, your Honor. Thank you.

I'd like, if I can, to ask the government's assistant, I'd like to look at 1609AT again.

THE COURT: Do you want the jurors to retrieve their binders?

MR. FASULO: Yes.

THE COURT: So this is the transcript you looked at earlier. If you would all please pull your binders out or look on the screen.

MR. FASULO: And if I could have the first page, please? Sorry.

BY MR. FASULO:

Q. This is a transcript of April 30, 2019, between Lisa Giannelli and Norman Morford.

Would it be fair -- doctor, you don't know who Norman Morford is?

A. No, I don't.

MR. FASULO: Can we now look at the transcript, please, page 1.

Q. Do you remember looking at this transcript and hearing it played to you during your direct examination?
A. Yes, I do.
Q. And do you remember a statement that you made regarding this transcript regarding whether or not it established the VCPR relationship?
A. Not specifically. But I believe I probably did say that.
Q. And would it be fair to say -- and the government said in their question to you -- that if a vet was part of this conversation, it would have a different import to you, correct?
A. Possibly.
Q. Right. And is it also fair to say that this is a small transcript -- small snippet of a full transcript as far as you know?
A. As far as I know, I just know what I am shown.
Q. Right. And you don't know whether or not this Norman --
MR. FASULO: Go back to the first page again.
Q. Whether or not Norman Morford had any other conversations with the vet, Dr. Fishman, do you?
A. I don't.
Q. And you don't know what the relationship he had with the animals that Norman Moford was ordering these materials for?
A. I don't, but they don't --
Q. Do you or do you not?
THE COURT: That is a yes or no, Dr. Bowman. Do you

know what the relationship --

Q. Between Dr. Fishman and Norman Moford or his patients, his horses were, you don't know that relationship --

A. No, I don't.

Q. You don't know if it was an existing relationship?

A. No, I don't.

Q. And you don't know what information Moford would have given to Fishman before he made this call, if any? You don't know that?

A. I don't.

Q. And all of those things would have to be considerations before you would be able to say whether there was a VCPR relationship between Dr. Fishman and the horse that Norman Morford was ordering for.

A. I think there are certain pieces of information that would have to be included in this call in order to document that there was a VCPR, including the names of the patients and reference to a conversation with Dr. Fishman, because I don't know how the person selling the drugs would know that he had given his okay unless she was told that from the owner or she asked for that information.

Q. Or if she was told that from the vet?

A. That seems unlikely to me.

Q. I'm not asking you whether it seems unlikely. My question is you don't have the basis to make that judgment; is that fair

to say?

MS. MORTAZAVI: Objection.

A. The information I can see in this --

THE COURT: Overruled.

From what's on this transcript, do you have the information you need to make that determination? You can answer that.

THE WITNESS: My personal determination would be this fails to meet the VCPR.

Q. If you were hypothetically to find out there was a conversation and an examination of the animal that Norman Moford had by the doctor before this conversation took place, would that be a consideration in your determination?

THE COURT: Is this a hypothetical question?

MR. FASULO: Yes. That's a hypothetical.

A. It could be.

Q. And if, in fact, hypothetically there was a phone call between Dr. Fishman and Lisa Giannelli regarding this upcoming call from a Norman Morford describing what the call would be about and what Mr. Morford would want, that would be another consideration that would go into your determination that there was or was not a VCPR relationship?

A. It could.

Q. So without that information, you're not able to make a judgment right here as whether or not there was a VCPR

relationship between the doctor and this particular client, or his horses?

MS. MORTAZAVI: Objection. Asked and answered.

THE COURT: Overruled.

A. I'm sure that there could exist other information --

MR. FASULO: Judge, I asked for a yes-or-no.

A. -- would lead me to come to a different conclusion. I can only base it on what I know.

Q. Very well. Thank you.

MR. FASULO: I'd like to go to transcript number 182. This is a phone call, intercepted line, on 4/27/2019 between Lisa Giannelli and Timothy Collins.

Q. Can we go over -- Doctor, you also looked at this conversation, correct?

A. I did.

Q. And without having any other context, without knowing anything else about this conversation -- let me withdraw that question.

And, doctor, you don't know if there were other conversations between Tim Collins and Dr. Fishman before this conversation, do you?

A. No, I don't.

Q. Do you know if Tim Collins' horse was ever evaluated by Dr. Fishman?

A. From the information presented today, I don't know.

Q. And do you know whether or not there was actually a relationship between Tim Collins' horse and Dr. Fishman under the VCPR?
A. No, I don't. And I also don't know if there's relationship between Lisa Giannelli and Dr. Fishman.
Q. Thank you.
Next, I'd like you to look at 185.
Doctor, I direct your attention to the screen. This is Government Exhibit 185T, a conversation between Lisa Giannelli and an unknown female.
MR. FASULO: Can we turn to the first page, please?
Q. Take a moment to reflect your recollection about this conversation. Do you know who Nancy Hargis is?
A. No, I don't.
Q. Do you know if she's a vet or not a vet?
A. No, I don't.
Q. And do you know whether or not Nancy Hargis had had any conversations with Dr. Fishman about her horse or needs of her horse prior to her conversation with Lisa Giannelli?
A. I don't even know if she knows Dr. Fishman.
Q. Do you know whether Lisa Giannelli had any conversations with Dr. Fishman before she sent out the order?
A. I don't.
Q. Okay. And would you agree that all those factors would be factors that need to be considered in determining whether

there's a valid VCPR relationship?
A. If they are available.
Q. If they happened?
A. Yeah. Yeah, if they happened.
Q. Thank you.
Transcript number 171. Again, this is a May 1st, 2019, conversation between -- transcript between Lisa Giannelli and Tyler Buter. Take a look at this transcript, Doctor.
And just once again, briefly, it's fair to say that you don't know what transpired before this snippet of a conversation, correct?
A. No. I have no way of knowing what happened before.
Q. And you don't know whether Tyler Buter had a conversation or had an existing relationship with Dr. Fishman?
A. There's no mention of Dr. Fishman in this.
Q. So you don't know that?
A. I don't know either way.
Q. And you don't know -- and this is a portion of that conversation, correct, as far as you know?
A. As far as I know.
MR. FASULO: And that's it for this. Go to 127B.
Q. This is the transcript, 127B. The date is 4/4/2019 between Seth Fishman and Nick Devita.
Do you remember seeing this transcript before?
A. Yes, I do.

Q. And, again, you don't know who Nick Devita is?
A. No, I don't.
Q. And Seth Fishman, you have learned is a veterinarian, correct?
A. Yes. He is a veterinarian as far as I know.
Q. And this is a conversation between the vet and this person named Nick Devita. In this conversation, is it fair to say that the doctor is talking about what the potential use of the bleeder could be if I draw your attention to line 8?
A. Yes.
Q. And is it clear from this conversation that Dr. Fishman was also telling -- let me read on number 10, Fishman says: It's using much newer, more let's just blood bioengineered amino acids, correct?
A. Blood is not in there. But, yes, that's what it says.
Q. I'm sorry. Bioengineered amino acids.
A. That's what he says.
Q. You would agree with me that this is alone a part of a conversation; this is all you saw when you testified, correct?
A. Correct.
Q. And you don't know what the conversation was before this or after this relating to what was discussed in this conversation, correct?
A. That is true.
Q. And you don't know whether the animal that Mr. Devita may

have had was or was not an existing patient or existing patient under Dr. Fishman's care; do you know that?

A. Not from this conversation.

Q. I'd like to go to 1605AT. It is a conversation between Lisa Giannelli and Joshua Parker dated April 25, 2019.

MR. FASULO: You can go to the next page.

Q. Do you remember being shown this conversation during your direct examination?

A. Yes.

Q. And at this point, I think earlier you stated you don't know if Lisa Giannelli worked for Dr. Fishman. If you look at line six, can you read that line?

A. In this conversation, she says she still works for Dr. Fishman.

MR. FASULO: Okay. And can I have the whole -- thank you for that.

Q. And, in fact, if you read line 11, this indicated to you that Dr. Fishman didn't answer and I sent him a text message and he still hadn't responded. Is that what line 11 says?

A. That's what it says.

Q. Do you know whether JP ever made contact with Dr. Fishman or if Lisa Giannelli made contact with Dr. Fishman before she dispensed or sent these items to JP?

A. I don't know whether she tried or didn't try or -- no, I don't.

Q. And would the fact that Fishman -- would it affect your opinion that you gave in court about the VCPR relationship -- would it affect your opinion if you were to find out that there were conversations or knowledge or examinations done by Dr. Fishman before these items were sent out?

THE COURT: Are you asking hypothetically or --

MR. FASULO: Hypothetically, Judge.

A. Well, if there were examinations carried out and diagnoses made that would affect my determination. I don't believe that's the case based on information.

Q. Well, the information you have is only the transcript; is that right?

A. Presented here today.

Q. You don't have any reason -- you don't have any other information to guide you on that; is that correct?

A. Can I make reference to anything in the past?

THE COURT: If you have other information, that's the question. So you can answer.

Q. Specifically related to this conversation and this transaction?

A. Not this specific transaction.

Q. Well, that's what we're talking about, aren't we --

A. No, we're talking about VCPRs with Dr. Fishman and his patients.

Q. No, I was talking about specifically about VCPR

relationship between Dr. Fishman and JP, who's labeled in this conversation. And do you have information regarding that relationship that affects your opinion here today specifically about that relationship.

A. The information that I have is that Dr. Fishman didn't have a valid veterinarian-client-patient relationship with any of the horses for which he was prescribing drugs.

Q. But you don't know that from any of the facts as it relates to this particular individual, isn't that fair to say?

A. No.

Q. You don't know if he ever went to the farm where this horse was; do you know that?

A. The information I have would --

THE COURT: Let her finish.

MR. FASULO: I object to the answer. She can only base her answer on what information she actually knows.

THE COURT: That is correct. That is correct, Dr. Bowman. But you can answer based on what you actually know.

THE WITNESS: Your Honor --

THE COURT: Not what you have been told by someone else.

MS. MORTAZAVI: Could we have a sidebar on this point in particular?

THE COURT: Sure.

MS. MORTAZAVI: Thank you, your Honor.

(Continued on next page)

(At the sidebar)

MS. MORTAZAVI: Your Honor, my issue with how this question is being phrased -- it's not specific as to what types of information Mr. Fasulo is trying to elicit. We've obviously had conversations about this case with this witness, and so she knows information, it is just information that I've transmitted to her. It's not materials that Mr. Fasulo is referencing which are sitting in on in-person meetings or transcripts or e-mails or whatever else he might be referring to.

THE COURT: I understand that. But the problem is she can only testify to what she personally knows, or you get an opportunity to -- hold on -- to redirect you can ask about information that she relied upon or what was made available to you or what she might have known.

Having said that, Mr. Fasulo, I keep asking, is it hypothetical?

MR. FASULO: It is. I keep saying yes.

THE COURT: I know that, but I shouldn't have to keep asking it. I just don't want the record -- I know you wouldn't do it intentionally, but I don't want the record to misrepresent or create an impression on something that you know to be contrary to the facts.

MR. FASULO: Correct, Judge. That's why I'm saying it's hypothetical.

THE COURT: That's what I'm saying.

MR. FASULO: I'm sorry.

MS. MORTAZAVI: Your Honor, so my request would be Mr. Fasulo just punctuate his question because --

THE COURT: What do you mean by punctuate?

MS. MORTAZAVI: I think clarify his question because I think this witness is just getting confused.

THE COURT: I think she's holding her own.

MS. MORTAZAVI: Okay. All right.

THE COURT: Ms. Mortazavi, you can object if you have an objection.

(Continued on next page)

(In open court)

MR. FASULO: If I may, your Honor?

BY MR. FASULO:

Q. Let me ask again, hypothetically, if there was an ongoing relationship between Dr. Fishman and the animal that JP represented, and that ongoing relationship included Dr. Fishman having a relationship with the horse, understanding the horse, and doing what a vet does, would that affect your judgment as to whether or not it was a VCPR relationship?

A. Yes, it would. But that is hypothetical.

Q. That is hypothetical.

THE COURT: That's what the question said.

Q. That's what I asked.

A. Yes.

Q. Thank you.

Now, let me ask you specifically about some of the exhibits that you looked at during your direct examination of other exhibits that are in evidence here today.

MR. FASULO: First of all, I'd like the government, if I may ask again, if you can publish Government Exhibit 5007. And if we can zoom many on the second row of that exhibit. Can we get a little bit closer on that? Is it possible? Thank you.

Q. Now, doctor, during your direct examination, you talked about a number of different products; do you remember that?

A. Yeah.
Q. Are you familiar with the product that's all the way on the left? I'm sorry. Let me just get rid of that. One second.
I'd like to direct your attention to that product. Can you read the name of that product?
A. It looks like it's Flunixamine.
Q. What's Flunixamine?
A. Well, the active ingredient Flunixamine is flunixin meglumine, the same as Banamine. I can't see that label well enough, and I haven't memorized the brand names for every approved flunixin meglumine, so I can't tell you if that's an approved product or an unapproved product.
Q. So you can't tell us that right now?
A. From that picture, I can't.
MR. FASULO: Can we get it a little bigger?
A. It's so blurry when it's blown up.
Q. We don't have it in the courtroom, so I'm doing the best with the picture that we have.
Would you agree, at least, that Flunixamine -- there is an approved product of Flunixamine on the market?
A. As I just said, I can't tell if that's the approved product. There are approved products with that active ingredient, but it's so blurry, I can't read it.
MR. FASULO: If we can go back to the bigger picture.
Q. I'd like to draw your attention now to -- here we go.

THE COURT: Are you still on the same shelf or were you trying to move down a shelf?

MR. FASULO: This is where I wanted to go, Judge. If we can make this a little bit bigger, that would be great.

Q. Can you see the name of the product, at least here, that I'm marking with the blue line?

A. The shelf label reads Tridex.

Q. What is Tridex?

A. I do not know.

MR. FASULO: Can we go to the bigger picture again and go to the next shelf? Thank you.

Even with my eyes it's hard to see. If we can zone in on that a little bit and see if it comes out?

Q. Can you see the name of that product?

A. Yes. It's Agrimycin 200.

Q. Are you familiar with that product?

A. I am.

Q. Are you familiar with this lab that's labeled underneath?

A. AgriLabs, yes.

Q. What is AgriLabs?

A. It's an approved sponsor of multiple new animal drugs.

Q. What is Agrimycin?

A. Agrimycin is a formulation of oxytetracycline, 200 milligrams per mil.

Q. Are you able to determine whether this is an approved

product or not an approved product?
A. It is an approved product. I can't -- it's so blurry, I can't tell you that, but I'm pretty sure that at the very top it says NAD-something.
THE COURT: Is it easier to read if we make it less large?
THE WITNESS: Maybe. You're blowing it up so big.
MR. FASULO: I'm going to go to the next shelf, your Honor. Thank you.
Q. I'm going to ask you to look at this product I'm circling right here, these two products.
A. Okay.
Q. And I apologize about the visual. We don't have the product here in the court for various reasons. It's the easiest way to show it to you.
Can you see the name of that product?
A. Yes, it's Adequan.
Q. Are you familiar with that product?
A. I am.
Q. Is that an approved product?
A. Yes, it is.
Q. The one next to it, can you see that product.
A. That's another version of Adequan.
Q. Is that an approved product?
A. Yes, it is.

MR. FASULO: If we can go to the big screen, please, if we can go to the lowest level?

Q. I'd like to draw our attention to this product right here. Can you read the name of the manufacturer of this product?

A. Yeah. This is Henry Schein.

Q. What is Henry Schein? Who is Henry Schein?

A. It's a veterinary distributor company.

Q. Is it on the approved list from the FDA?

A. Henry Schein?

Q. Yes.

A. They're a registered company, if that's what you mean.

Q. Right. And are they -- on this, do you see the product name here?

A. Yeah. Thyroxine.

Q. Are you familiar with that product?

A. I am.

Q. Is that an approved product from the FDA?

A. No, it isn't.

Q. What about this product have you indicated makes it not an approved product by the FDA?

A. Well, I can't read the label because it's too blurry, but I'm familiar with that product, and it's not an approved product.

Q. And on this product, you see that it's produced by this -- or distributed by this manufacturer, correct?

A. Yes.
Q. And if a doctor wants to describe this product, is it permissible for the vet to prescribe this product even though it's not approved?
A. Yes.
Q. And is it permissible for Henry Schein to distribute this product to a vet to be distributed within the vet's discretion under the guidance of state and federal statute to animals?
A. Well, under the state statutes, it may very state to state. We have given this product -- this specific product enforcement discretion for marketing because it's considered medically necessary in the treatment of horses with hypothyroidism. So until there's an approved version for administration to horses, we're allowing the distribution of the unapproved product.
Q. That's something a veterinarian needs to know before they prescribe this or dispense this product; is that correct?
A. Not really.
Q. Well, if it was not conditionally approved, as you just stated -- Let me rephrase the question. I misstated.

Since it's an unapproved product, which you're allowing vets to dispense, it's important for the vets to know that you are allowing them to dispense it under certain circumstances; would you say that's important to know?
A. No. Because there's no alternative.
Q. Right. But there's nothing that the FDA does that would

prohibit a vet from dispensing this product under the right conditions; is that fair to say?

A. The FDA doesn't object to a veterinarian dispensing this product under the appropriate conditions.

Q. But it is labeled as an unapproved product, right?

A. It is an unapproved new animal drug.

Q. Now, I'd like to now --

MR. FASULO: That's fine with this particular line. I'd like to go to Government Exhibit 5014, also, that's been entered into evidence.

Q. And you see again -- do you see the product again here that's circled in blue?

A. Yeah, the Banamine, or the one next to it?

Q. I meant just the Banamine.

A. Yes.

Q. Are you familiar with that product?

A. Yes.

Q. Are you familiar with the manufacturer of that product?

A. Merck, yes.

Q. Is this product approved by the FDA?

A. Yes, it is. And if you look at the box --

THE COURT: You've answered the question.

A. It's right there.

Q. And you stated earlier in looking at specifically -- and it says on this product it's FDA approved. Is that what you were

going to say -- it's within the vet's discretion to prescribe this product as necessary?

A. Yes.

Q. Okay. I want you to look at Government Exhibit 5011. I'd like to draw your attention as best we can to this product we circled.

Now, doctor you talked about labels during your direct examination; do you remember that?

A. Yes.

Q. Do you see a label on this product, right?

A. Some of a label.

Q. Some of a label, correct. And you see that there's an -- well, there was one label that is here and here, which seems to go around the bottle, right?

A. Yes.

Q. And there's another label here, correct?

A. Yes.

Q. And when you were looking at the sample labels that were displayed to you, those were on a flat sheet of paper, some of those were on a bottle, correct? Do you remember seeing those?

A. Some were; some weren't.

Q. Do you remember seeing the ones on a bottle?

A. Yes.

Q. And, additionally, to those types of labels, there's another label here, correct?

A. Yes, there is.
Q. Are you able to make out the contents of that label?
A. Not much of it. Some of it.
Q. Okay. And can you tell me what purpose this part of -- let me just do this. Do this.
MR. FASULO: And if we can highlight that, that would be great. I don't know if it's going to get blurry. Hopefully not.
Q. In terms of the labeling -- necessity of the labeling process, pursuant to the FDA, what ingredients does this label have that comply with the labeling process of the FDA.
A. I can't see enough of this label to say.
Q. Does it have the name of a physician who has prescribed this medication?
A. There's more than one type of label.
MR. FASULO: Excuse me, judge. My questions was --
THE COURT: You need to answer the question that was asked, Doctor. Does it have the name of the veterinarian who prescribed it? It says physician who's prescribed this medication.
THE WITNESS: Yes.
Q. Does it have a prescription number?
A. Yes, it does.
Q. Does it have a quantity?
A. Yes.

Q. Does it list the active ingredients as well as the -- does it list the API ingredients?
A. It lists some API ingredients. I can't read all of it, and I don't know if that's everything.
Q. Okay. And you would have to do a further GRASE analysis to figure that out?
A. I need to be able to figure out all of both labels.
Q. Before you said that, in terms of that part of the label, my question is in terms of that part of the label, the active ingredients and -- the active ingredients, that's something that you learned during the time that you've become a doctor and become a representative at the FDA, correct?
A. Yeah. It's something I've learned.
Q. It's not something a seven-year-old knows, right?
A. Correct.
Q. Okay. And that's part of the labeling process you evaluated, correct? The ingredients?
A. Yes.
Q. So when you said a seven-year-old can figure out what a label should look like --
A. I never said that.
Q. Oh, okay. So you would agree that you need to have a certain expertise to make a determination whether or not a label is in compliance or not compliant with the FDA rules and regulations?

A. You can look at our guidance documents and trace what's required on each label.
Q. But as to the specificity of the needs of the label, you would need to have a certain expertise, specifically, as it goes to the listing of the ingredients of the product?
A. Or you could call us and ask.
Q. But eventually, you wouldn't know that unless you had a basis to understand the chemistry that went into these ingredients; wouldn't that be fair to say?
A. No.
Q. Hypothetically, if an individual looked at this label, would they be able to determine what API and what ingredients needed to be listed on this product without any other basis for making that determination?
A. I believe they would make that determination based on other labels that they've seen.
Q. Right. But in terms of the specific milligrams, the specific chemical compounds that are put into this label, you would need to have some scientific basis to understand what's being said here?
A. I disagree.
Q. Well, for example, this word -- tell me what that word is.
A. Triphosphate.
Q. Triphosphate. You would need to know what triphosphate was and what its intended use was when you were labeling this

product; wouldn't you?
A. Well, no, not really. You would need just --
THE COURT: You've answered, Doctor. You said no.
Q. So, Doctor, is it your testimony --
MR. FASULO: Withdrawn, judge.
Q. Let's look -- let me go to the bottom line here.
Would you agree that this is one of the requirements in the labeling process of medication -- prescription medication, the last line there?
A. It is.
Q. And would that be necessary for this particular medication?
A. Yes. I think it would be. But, again, I can't read the whole label, so it's hard to draw conclusions.
Q. I'm just asking about this -- that part.
A. Well, I need to know what else is in the product in order to say whether that's required.
Q. And once you would know what else is in the product you'd have to look at those ingredients, compare them to what type of ingredients they were, and then make that determination, right?
A. And look at the intended use, the directions for administration, and the indications.
Q. And all of which you have been trained to do, correct?
A. Anyone who reads labels knows those things.
Q. Okay. Thank you.
I'd like to go to one more exhibit, if I may. I'd

like to go to Government Exhibit number 5012. I'd like to focus your attention on -- what happened here? One second.

Can you see this label?

A. Yes.

Q. Do you see a prescription number on this particular item?

A. Yes, I do.

Q. And do you see also the name of the physician?

A. The veterinarian, yes.

(Continued on next page)

BY MR. FASULO:

Q. Do you also see the name of the patient that this medication was going to go to?

A. Yes.

Q. And do you also see this -- can you also see this warning right here?

A. I don't think that qualifies as a warning, but I see the statement you're referring to.

Q. And what is the purpose of that statement from the FDA's perspective?

A. I don't think the FDA has a perspective on that particular statement. That may be something that the pharmacy board requires.

Q. Underneath that, you see this, correct?

A. Yes, I see that.

Q. And that is an expiration date, right?

A. Yes, it is.

Q. And above the expiration date there is a term N-butyl alcohol, 21 percent?

A. Yes.

Q. What is that?

A. It's a type of alcohol.

Q. And what's the purpose of that particular drug?

What's the purpose of that ingredient?

A. That probably is -- that is the drug and N-butyl alcohol 21

percent and they're probably using that as a diluent for certain other drugs. I couldn't tell you what they're using it for.

Q. And you also see here there's INJ. You see that. Does that mean injectable?

A. It does.

Q. And you also see up top here where I put an X, a name of a pharmacy. Do you see that?

A. Yes.

Q. Are you familiar with that pharmacy?

A. I've heard of them.

Q. Do you know if they are FDA approved?

A. There's no such thing as an FDA pharmacy.

Q. And you see over here there's an address up there, 221. I don't think we have another view of this bottle. I looked. I don't see.

And on the bottle there's a lot number, correct?

A. Yes.

Q. And that's in order to trace back this product if there was something wrong with it, is that why the lot number's there?

A. That's why the lot number is there.

MR. FASULO: Just a few more questions, Judge. Just one or two more questions.

THE COURT: That's fine. You're finished with the exhibit from the Boothwyn pharmacy.

MR. FASULO: Yes.

THE COURT: You can take that down, Ms. Jung.

Thank you.

BY MR. FASULO:

Q. If we can have 1111 shown to the jury, Government Exhibit 1111.

Doctor, you said you looked at this exhibit earlier, correct?

A. Yes, I did.

Q. And did you do a GRASE analysis?

A. GRASE?

Q. GRASE analysis on this particular item?

A. I did.

Q. And I think in your direct testimony you indicated that it didn't pass the GRASE test, per se?

A. It's not generally recognized as safe and effective.

Q. Would it be fair to say that a veterinarian would be able to dispense this medication even though it didn't pass the GRASE test under any circumstance?

A. For the intended use as we understand it, there would be no way to dispense this product under the 21 CFR 530 regulations.

There is nothing in the regulations that allows for the compounding of animal drugs from bulk, and this is an unapproved new animal drug that isn't generally recognized as safe and effective. It's misbranded because it lacks so much

labeling information that would be needed for its use. What else can I say?

Q. At the end of the day, this drug is available to the veterinarian. In the veterinarian's discretion based on the regulations to prescribe if he, in his professional opinion, believes it to be necessary and complies with the FDA regulations?

A. My point is, there's no way to comply with the FDA regulations for this drug, not as it sits right here now.

Q. So let me ask you something, another thing on this drug, do we know who -- does this indicate to you who prescribed this medication?

A. No.

Q. Does it indicate to you where this medication came from?

A. No.

Q. Does it have any indication of its origin or its potency as far as you can tell from the label?

A. I think it had some information about the potency on the other side of the label. But from what I can see right now, no.

Q. I'd like to look at Government Exhibit 1113.

A. It lists the two components, but doesn't list the concentrations.

Q. And when you say the two components, would that be the B4 and B10?

A. Beta 4 and Beta 10.
Q. Is Beta 4 an approved drug from the FDA?
A. No.
Q. Is Beta 10 an approved drug from the FDA?
A. No.
Q. And 1114, my last one.

Doctor, you see what's on the screen right now in front of you?

A. I do.
Q. Are you familiar with the medication?
A. Factrel, yes.
Q. Is that an approved drug from the FDA?
A. Yes, it is.
Q. Doctor, in terms of who may actually administer these drugs once they are dispensed, is it fair to say that it may be, even if it's a prescription drug, that there are cases where a trainer can administer these drugs under the auspices of a vet?

MS. MORTAZAVI: Objection, vague. "These drugs."

THE COURT: I'm sorry.

MS. MORTAZAVI: Vague as to which drugs.

THE COURT: You want to clarify.

Sustained.

Q. Doctor, you talked about administering drugs on direct examination, correct?
A. Yes.

Q. And you talked about some drugs had to be administered by a license veterinarian, correct?
A. Correct.
Q. Isn't it also true that it can be administered -- some of those drugs could be administered by a trainer or somebody under the direction of a licensed vet?
A. Yes, it is.
Q. And that's because we don't have enough vets?
A. No, that's not why.
Q. But isn't it true that we have -- well, why is it?
A. The reason that is allowed is because the veterinarian makes the determination whether a specific individual is capable of administering the drug as directed by the veterinarian.

And if he makes that determination, then he can prescribe that drug for an animal and dispense it to the individual with the directions for use.

Q. And that determination is within the sole discretion of the vet who's prescribing that job?
A. Within a valid client-patient relationship.
Q. My question is, is that discretion -- is that the sole discretion of the veterinarian to make that determination?
A. Within the veterinarian-client-patient relationship.
Q. Doctor, are you familiar with the code, the Delaware code as it relates to the definition of what a valid

veterinarian-client-patient relationship is?
A. Not specifically, no.
Q. And you would agree with me that that code, the Delaware code, is what would guide veterinarians who are licensed in the state of Delaware treating animals, do you agree?
A. The first thing that guides the veterinarian in whether to dispense a prescription animal drug is whether the individual client or person charged with that animal's care is capable of administering the drug as directed.

And then there are a number of other decisions that have to be made, the practice act would be one, racing rules would be another, it depends on the use of the horse and the stage of its life. There's many factors that go into that decision.
Q. In terms of prescribing the medications that would be based on the veterinarian's judgment based on the rules that he was following within the individual states as it relates to the veterinarian-client-patient relationship?
A. It relates to all those things I just said.

MR. FASULO: Okay. No further questions.

THE COURT: All right. Thank you.

Is there redirect, Ms. Mortazavi?

MS. MORTAZAVI: Yes, your Honor.

REDIRECT EXAMINATION
BY MS. MORTAZAVI:

Q. Dr. Bowman, I just have a few questions for you to follow-up on a few of the statements that you judge made to Mr. Fasulo.

Dr. Bowman, you stated just a moment ago that some drugs can be administered by trainers or others under the supervision of a veterinarian; is that right?

A. Yes.

Q. And you were speaking directly based on veterinarian practice principles; is that correct?

A. Yes.

Q. You were not opining on any states racing rules, were you?

A. No.

Q. Ms. Jung, could you please pull up Government Exhibit 1111, 1112 and 1113. These are the bottles of TB-7 -- photographs of the TB-that were taken in the search of Christopher Oakes's barn.

Dr. Bowman, you were asked some questions about this label, do you recall that?

A. Yes.

Q. And you stated there's no manufacturer information or contact information here, correct?

A. Correct.

Q. Ms. Jung, could you please focus on Government Exhibit 1112, if you could expand that.

Dr. Bowman, do you see a watermark on this label that

appears to be a horse head logo?
A. Yes.
Q. Ms. Jung, you can take this down. Thank you.
If you could please pull up Government Exhibit 5011, if you could focus on the bottle to the far left, Ms. Jung.
Dr. Bowman, do you recall being asked some questions about this prescription label?
A. Yes.
Q. Do you recall starting to say that there were many different types of labels?
A. Yes.
Q. Could you explain your answer?
A. Yes. I think we're all familiar with receiving drugs from the pharmacy and the pharmacy is required to apply a label that specifies, among other things, who prescribed the drug, what the -- how many tablets or how much is in the container, who it's for, how you're supposed to administer it in the simplest of directions, that kind of information.
That doesn't substitute for or replace the required prescription drug labeling that would come on the original container.
In those cases, for example, in this picture, this image, they're using the original container and then applying that pharmacy label over top of it which is commonly done with a lot of animal drugs because you're gonna use a 100 ml to

treat a single horse over time. So, you definitely would want the whole bottle, so they're not going to subdivide that this into smaller quantities like they would in a human pharmacy if you just needed 10 mls to treat a child, so you see multiple labels on something that's dispensed.

Q. Ms. Jung, could you please display Government Exhibit 5035.

Dr. Bowman, we just looked at a bottle of TB-, do you recall that?

A. Yes.

Q. Do you see the sticker here that says TB-7?

A. Yes.

Q. Ms. Jung, if you could take this down and please pull up Government Exhibit 5012.

Dr. Bowman, do you recall being asked questions about this particular label?

A. Yes.

Q. Do you recall being asked questions about the so-called patient name on this label?

A. Yes.

Q. Hypothetically, if a prescription drug is obtained in the name of one horse, can it be legally dispensed to a different horse?

A. No, not that I'm aware of. There could be some variation in the pharmacy rules because this was prepared at a pharmacy, so that's a pharmacy label.

Q. Ms. Jung, if you could take this down and please display Government Exhibit 5014 and focus on the bottle of Banamine here.

Dr. Bowman, you referenced that there was some markings on this label indicating that this was approved by FDA?

A. Yes.

Q. That's the line that appears below NADA number 101-479?

A. Yes.

Q. You also testified that you're familiar with the company Merck, correct?

A. Correct.

Q. Going back to that NADA language, what does that acronym stand for if you're familiar?

A. That stands for new animal drug application, and the number that follows that is the official number for that product.

Q. And are all approved products given a number like that?

A. Yes.

Q. And do approved drugs have to include statements like that?

A. Yes. Well, qualify that.

If we ever get our new regulations, that will be required for everyone. At present, it's recommended, but not required. Nearly all approved sponsors do put it on their label, but you will find some examples of product that are approved drugs without that language on the label.

Q. Ms. Jung, can you please display side by side Government Exhibit 5014 and Government Exhibit 1220 which is the bottle of BB3 that was seized from Jorge Navarro's residence.

Are there differences in the labels between the approved drug Banamine and BB3?

A. Yes.

Q. Can you name three examples?

A. It lacks the cautions, the precautions, including the caution statement, the prescription legend. It's lacking the NDC number which is how you know that it's properly listed with FDA, and it's lacking the established name for the ingredient.

Q. Ms. Jung, could you display side by side Government Exhibit 5014, the approved version of Banamine and Government Exhibit 1022. If you could focus on one of the portions of the Government Exhibit 1022.

Dr. Bowman, looking at these two labels side by side, can you list three differences between the approved drug on the left and ACTH on the right?

A. So, it lacks the manufacturer identifying information. It lacks the prescription legend and it lacks the caution and precaution statements.

Q. Ms. Jung, if you could take these exhibits down. If you could please just play Government Exhibit 5007 and focus on the second shelf, Ms. Jung.

Dr. Bowman, do you recall being asked questions about

these drugs generally?
A. Yes.
Q. Which of these drugs require a prescription?
A. Of the ones whose labels I can read which is I think three, they all require prescriptions.
Q. Ms. Jung, could you please go back to the original image and focus on the third shelf that appears here.
Dr. Bowman, could you tell us which of these drugs would require a prescription, if any?
A. They all require a prescription.
Q. Are you familiar with ventipulmin?
A. Yes.
Q. What is that?
A. That's a clenbuterol drug. It's to improve breathing.
Q. Ms. Jung, if we could focus on the fourth shelf.
Dr. Bowman, are there any drugs here that would require a prescription?
A. I hate to rely on the shelf tag because I'm not confident that the shelf tags are accurate, but the ones who labels I can read, which are five, and all of them require prescription.
Q. Ms. Jung, if we could focus on the bottom, going back to the original exhibit focusing on the very bottom to the right.
Dr. Bowman, do you recall being asked questions about Thyroxine L powder?
A. Yes.

Q. Before you were asked those questions, correct?
A. Yes.
Q. And you were already aware that the FDA exercises enforcement discretion with respect to this powder, correct?
A. Yes.
Q. And you were already aware of the distributor of this powder, correct?
A. Yes. There actually should be more than one distributor.
Q. And can you remind us what condition Thyroxine L powder?
A. Thyroxine L powder is used to treat hypothyroidism in horses and other animals, but not the powder form.

It had been marketed without approval for people and animals for many, many years, and it came to the attention of the FDA -- and this is all out there publically -- that it actually wasn't being manufactured to a satisfactory standard so that it was always the same which was causing problems, and treating patients, human and animal patients for thyroid deficiency.

So we now have approved human products and we have approved products for dogs, but nobody's gotten an approval yet for horses, so until they do, we've exercised enforcement discretion over this product, so there's something out there to treat horses with.

Q. And you stated in your testimony that you are familiar with Henry Schein, the distributor that appears on this label,

correct?
A. Yes.
Q. Were you familiar with Equestology before you were contacted to perform a GRASE analysis?
A. Only in the context of looking at unapproved drugs for potential enforcement activities.
THE COURT: Ms. Mortazavi, you want to find a good breaking point, please.
MS. MORTAZAVI: Your Honor, I'll ask one more question and I think that would be a good breaking point, your Honor.
THE COURT: Sure.
BY MS. MORTAZAVI:
Q. Dr. Bowman, you were asked some questions about several calls and transcripts that I had originally reviewed with you in your direct examination. Do you remember that?
A. Yes.
Q. And at that time when I asked you those questions, you had concluded that those calls did not reflect a valid VCPR, correct?
A. Correct.
Q. Can you just explain what led you to testify that those did not reflect a valid VCPR?
A. I was involved in a prior trial where --
MR. FASULO: Objection, Judge.
THE COURT: Hold on. Hold on. The objection is

sustained, so why don't we take a break at this point and I'll talk to counsel.

MS. MORTAZAVI: Thank you, your Honor.

THE COURT: And then we'll pick it up, Dr. Bowman, after the break.

Ladies and gentlemen, we're going to take our afternoon break. Please leave everything on your seats, and I remind you again, please don't talk about the trial or the testimony or the issues involved in the trial during your break.

(Continued on next page)

(Jury not present)

THE COURT: Dr. Bowman, you can step out. Just remember you're under oath.

Mr. Fasulo.

MR. FASULO: Judge, I objected because she's talking about a prior trial. If she was talking about the basis of her knowledge, I understand I opened the door to that.

THE COURT: Talking about the basis of her knowledge. You understand you opened the door.

MR. FASULO: I understand I opened the door. She talked about what she knew if it's relevant to what she testified to, I understand, but not the results of that trial or anything that happened at that trial because that's not really part of what she should be testifying here today about, whether there's a conviction or not a conviction.

THE COURT: Of course, she can't talk about the outcome.

MS. MORTAZAVI: I suppose I want to clarify Mr. Fasulo's position. I'm looking to clarify, your Honor, whether Mr. Fasulo would allow me to explore that a prior trial took place, but would not like me to explore who was on trial or the outcome. It seems like a minefield and I want to make sure I understand what Mr. Fasulo's position is.

MR. FASULO: I think there should be an offer of proof because I don't think the fact that there was a prior trial or

anything about a prior trial. Her knowledge is different.

THE COURT: The problem is, as you say, you kind of opened the door about the basis of her knowledge, and Ms. Mortazavi asked her what was the basis for your forming the conclusion, and she started to say what I learned from testifying in a prior trial, I think is what she started to say. Let me just scroll back.

Okay. As far as she got was, I was involved in a prior trial.

MR. FASULO: Judge, I ask for an offer of proof where this is going so we can avoid any kind of maybe minefields here.

MS. MORTAZAVI: Your Honor, my intention was not to elicit the prior trial. And if I'm permitted for this particular line of questions to ask a few more leading questions, specifically as to the lack of reference to Seth Fishman, lack of reference to a prescription or veterinarian. I tried to keep my question open-ended because it is redirect. But given this witness's experience in the litigation as a whole, I think it's appropriate that I ask leading questions at this point.

THE COURT: You mean in the conversation transcript, the lack of reference to A,B,C?

MS. MORTAZAVI: Correct.

THE COURT: The issue is, though -- that's all fine,

but Mr. Fasulo asked in his questioning hypothetically if this happened, would that influence your opinion. And she tried to offer more, and I thought that's what you were getting at, but you can ask those three questions.

And I agree that asking them in a leading fashion is probably the safest. Any objection, Mr. Fasulo?

MR. FASULO: No objection. Without hearing the question, obviously, but no objection to what we're going to do.

MS. MORTAZAVI: I think that resolves it, your Honor.

THE COURT: Okay. You can ask those three leading questions.

MS. MORTAZAVI: Thank you.

THE COURT: All right. Why don't we take a break. We told the jury about 3:15. I'll see everyone back then at 3:15.

(Recess)

MR. FASULO: Judge, before the jury comes in.

THE COURT: Yes.

MR. FASULO: I want to address our last conversation. I just want to be a little clearer. I believe that the government -- I opened the door. They can ask the witness what the basis of her understanding is, however if the basis of her understanding is hearsay, it is still objectionable, and I'm going to make the objection.

The mere fact she's told something about the

government is going to be objectionable, so it's what she knows still that she can testify to.

THE COURT: I thought we agreed though that Ms. Mortazavi wasn't going to do. She's going to ask three leading questions.

MR. FASULO: I wanted to review that.

THE COURT: You're correct about that.

MR. FASULO: If that comes up. I have no idea of the questions, and she doesn't have to tell me, so I don't know what they are.

THE COURT: I think she did tell you though.

MS. MORTAZAVI: I believe I did, your Honor.

THE COURT: Are we ready for the jury?

MS. MORTAZAVI: Yes, your Honor. I'll ask the agents to recall the witness.

THE COURT: Let's let Dr. Bowman get in before we get the jury out.

(Continued on next page)

(Jury present)

THE COURT: Government, Ms. Mortazavi, please.

Let me just remind you, Dr. Bowman, I know you know, but you're still under oath.

BY MS. MORTAZAVI:

Q. Dr. Bowman, I'm just going to pick up where we left off before the break.

I was asking you if you recalled during my direct examination and Mr. Fasulo's questions going over certain transcripts and going over certain calls and being asked to opine on them. Do You recall that?

A. Yes.

Q. And do you recall being asked whether there was or was not a valid VCPR?

A. Yes.

Q. And across the calls that you reviewed, apart from one example, was there a reference to Seth Fishman?

A. No.

Q. Was there a reference to a horse?

A. Not in any that I can recall, not by name at least.

Q. Was there a reference to any patient?

A. It was kind of a vague description in one of the calls, but it wasn't name.

Q. Was there any reference to a prescription?

A. No.

Q. Are those the sorts of things you would expect a veterinarian employee to ask about when discussing prescription drugs?
A. Yes, or at least remind a client that, you know, the approval of the prescriptions that they are hoping to get lands with the vet that will make the final decision, something along those lines.
Q. You were also asked questions about whether you knew of any calls or meetings that had happened before the calls that we reviewed took place. Do you recall that?
A. Vaguely.
Q. In any of the transcripts that we reviewed, was there any reference to a prior examination that you can remember?
A. No, not that I recall.
Q. Dr. Bowman, you were asked about FDACVM sending warning letters to manufacturers, do you recall that?
A. Yes.
Q. And do you recall being asked about letters sent to known manufacturers regarding drug labels?
A. Yes.
Q. Do you have to know the manufacturer of a drug in order to send them a warning letter?
A. Yes.
Q. Do you have to know the mailing address in order to send a warning letter?

A. Yes. In rare circumstances, we'll send an electronic warning letter if we have an email address, but not a physical address, but that's pretty rare.

Q. And if somebody turns in a bottle to the FDA that contains no manufacturer information, how are you supposed to know who manufactured that drug?

A. I ask my boss that a lot, and we do the research we can do, but often in many cases, it is impossible to figure out where the drug is manufactured.

Q. You were also asked questions about drug compounding, do you recall those?

A. Yes.

Q. Can you walk us through how a veterinarian would validly compound a drug?

MR. FASULO: Objection, vague.

THE COURT: Overruled. You can answer, Doctor.

A. Drug compounding is a complex area of pharmaceutical use and the way the animal law is written, all compounding from bulk drugs is illegal.

There is no provision in the statute or the law that allows for the compounding of animal drugs from bulk pharmaceutical ingredient there.

There is a provision in the law under 21 CFR 530 to manufacture or to compound for individual patients from approved human and animal drugs. So if you needed to dilute it

make it more -- dilute it for a small animal or you needed to crush a tablet into a powder and then mix it with a liquid to administer it as a liquid because of your patient, patient didn't tolerate pilling, but would tolerate liquid medication, something like that.

That said, we understand that there are rare circumstances when there is no approve product for which to compound a medically important drug for a specific animal, or even in very limited circumstances for office stock and our new guidance just came out, but it basically follows the same thread as our old guidance.

And we developed a list of drugs for which it's acceptable to compound from bulk for office stock. Other than that, compounding from bulk is very limited.

Q. Dr. Bowman, the new guidance you mentioned, when did that come into effect?

A. I believe it published in final the beginning of last week or the end of the week before.

Q. So within the last few weeks?

A. Yes, it was in draft. There was a draft version that was circulated for comment and then a final version just came out.

Q. That guidance was not in effect between the years 2000 and 2020?

A. No.

Q. Is drug compounding the same as manufacturing a brand new

drug from scratch?
A. No, not typically.
Q. Is a drug typically compounded from an existing approved drug?
A. That is the goal.
Q. And you testified that typically a compounded drug would have to be compounded pursuant to a prescription; is that right?
A. Yes.
Q. Would it have to be patient specific?
A. It has to be patient specific unless it's one of those drugs on the office stock list.
Q. Does that mean that the veterinarian would have to actually know the patient?
A. Yes.
Q. And I believe you also testified that a determination has to be made that no approved drug would be adequate before a drug could be compounded; is that correct?
A. That is correct.
Q. Did you also testify that there would have to be a determination that it would be necessary to compound a drug to prevent death or suffering?
A. Yes.
Q. Would an animal that's racing slowly be considered suffering?

A. No.
Q. Is compounding a drug to enhance a horse's performance necessary to alleviate animal suffering?
A. No.
Q. You were also asked several questions about whether it was ultimately up to a veterinarian's discretion whether or not to compound a drug? Do you recall those questions?
A. Yes.
Q. Are veterinarians subject to standards?
A. Yes.
Q. And that includes the requirement that there be a valid VCPR, that's what you testified to, correct?
A. Correct.
Q. Are veterinarians also subject to the Food Drug and Cosmetic Act or the FDCA?
A. Yes, wherever it applies to what they're doing.
Q. And if a veterinarian is manufacturing a drug, is that veterinarian subject to the FDCA?
A. Yes.
Q. In fact is anybody who is distributing drugs in the United States subject to the FDCA and associated regulations?
A. Yes.
Q. Does it matter whether or not they are a veterinarian?
A. No, it doesn't.
Q. You also testified that a veterinarian has to be licensed

in the states where they dispense medications as well as the states where they treat animals, correct?
A. That may have been -- I was assuming that they would dispense the medications at the time they saw the animals, so they would be in the same state at the same time.
Q. Assuming they were not in the same state at the same time, would a veterinarian have to be licensed in a state where the veterinarian dispenses medication?
A. First of all, I don't know why they would be dispensing medication to somebody in a different state.
MR. FASULO: Objection. Move to strike.
THE COURT: Please just answer the question that's asked.
A. I'm not sure.
THE COURT: It is stricken.
A. I'm not sure.
Q. What does it mean to dispense medication?
A. To dispense medication means to basically to give the medication to the person who's responsible for treating the animal.
Q. And how does that typically happen?
A. That typically happens at a visit. So the veterinarian is there, they make the diagnosis. They recommend the treatment and they dispense the treatment at that time.
Q. As in they physically hand it to the person, the client

they're dispensing the medication to?
A. That's most common.
Q. And if there isn't that in-person transfer, how else do people get prescription medications?
A. The veterinarian writes a prescription just like your physician writes a prescription, and then they take that prescription to a pharmacy that will fill it.
Q. Do veterinarians typically ship drugs?
A. None that I know of.
Q. Do drug manufacturers typically ship drugs?
A. Yes.
Q. You were also asked some questions about how often a veterinarian needs to consult with an existing patient. Do you recall those questions?
A. Yes.
Q. Does someone need to know the horse's name in order to determine whether it's an existing patient?
A. Yes.
Q. Is it typical for a veterinarian to take an order for a prescription drug without knowing the patient name?
A. No.
Q. Is it typical for someone working for a veterinarian to take an order for a prescription drug without knowing the patient name?
A. No.

MS. MORTAZAVI: No further questions, your Honor.

THE COURT: Thank you. Mr. Fasulo.

MR. FASULO: Just one, Judge.

RECROSS EXAMINATION

BY MR. FASULO:

Q. Dr. Bowman, you talked about -- rephrase.

Dr. Bowman, would it be fair to say that there's no federal law that prohibits a doctor from shipping a drug to a patient, a drug that he prescribed?

A. No.

Q. It is not prohibited?

A. No, it is not allowed.

Q. If I'm a doctor and I have a drug and I prescribed it for a client, I can ship that drug to the client?

A. No, not if it goes in interstate commerce. It goes in interstate commerce, it has to follow all the rules.

Q. And if it follows the rules, it would be okay, correct?

A. Yes.

Q. You don't know what those rules are, do you?

A. I know what the federal rules are.

Q. But you don't know whether or not -- what I'm asking you is, in the job of the veterinarian in taking care of an animal, he can ship a drug from his premises to the client and there's no FDA rule forbidding that; isn't that fair to say?

A. No.

THE COURT: No it's not fair to say?

THE WITNESS: No, it's not fair to say.

Q. What FDA rule addresses that issue?

A. They have to comply with the regulations on interstate commerce.

Q. And if they comply with the interstate commerce rules, then there is no FDA prohibition?

A. Well, it would depend on the drug and it would depend on the interstate commerce.

Q. So those two factors would go into play, but if they pass those requirements, the vet can ship that drug as far as you know?

A. I think there's too many hypotheticals. I can't answer that.

Q. Let me ask you a hypothetical then -- not a hypothetical.

Is it your testimony here today that a doctor is not permitted to ship a drug if the doctor follows both interstate commerce laws and the FDA regulations?

THE COURT: A veterinarian.

Q. The doctor being the vet?

A. Can I explain it. As if I'm the vet, I have a patient. My patient has moved to another state. I have a valid VCPR with that patient, but I'm not licensed in that other state, I cannot ship drug there.

Q. Say you are licensed in that state?

A. If I am licensed in that state as well as the state where I am, then as long as it meets all the other rules of a drug that's allowed in interstate commerce, I could ship it.

MR. FASULO: No further questions.

(Continued on next page)

MR. FASULO: No further questions.

THE COURT: Thank you.

MS. MORTAZAVI: Just one question, your Honor.

REDIRECT EXAMINATION

BY MS. MORTAZAVI:

Q. Dr. Bowman, I want to make sure I understand your last answer.

I believe you stated that if you were the veterinarian and you were in one state and you were shipping a drug to a separate state that you were not licensed in, you would not be allowed to do that; is that correct?

A. That is correct.

MS. MORTAZAVI: Thank you.

MR. FASULO: Nothing further.

THE COURT: All right. Thank you, Dr. Bowman. You're excused with the thanks of the Court.

THE WITNESS: Thank you.

(Witness steps down)

THE COURT: Mr. Gianforti or Ms. Mortizavi.

MR. GIANFORTI: Thank you, your Honor.

Before we call the next witness, can we read the remaining stipulations into the record?

THE COURT: Sure.

MR. GIANFORTI: Ms. Jung, can you please pull up Government Exhibit 9001, please?

All right. This is a stipulation between the parties, I will skip the preliminaries.

Paragraph 1: If called as a witness at trial, a record custodian for the entity T-Mobile Incorporated, T-Mobile, and for each of the government exhibits identified below would testify at follows:

T-Mobile provided law enforcement agents with historical location data, subscriber records, and other information for cellular phone with call number 561-270-9286, 9286 phone.

Government Exhibits 3600 and 3601 consists of account information and call detail records associated with the 9286 phone.

B: Government Exhibits 3602 and 3607 consists of call detail records and historical location information associated with the 9286 phone.

C: Government Exhibits 3600 through 3602 and 3607 are true and correct copies of records of T-Mobile, maintained by T-Mobile, and are records regularly conducted of T-Mobile that were made at or near the time by or from information transmitted by someone with knowledge of the information contained therein, kept in the course of regularly conducted activities of T-Mobile, and made as a regular practice of the activities of T-Mobile.

Paragraph 2: If called as a witness at trial, a

record custodian for the entity Verizon Wireless, Verizon, and for each of the Government Exhibits identified below would testify as follow:

Verizon provided law enforcement agents with historical location data, subscriber records, and other information for cellular telephone -- cellular phone with call number 302-222-2220, the 2220 phone. Government Exhibits 3603 through 3605 consists of account information and call detail records associated with the 2220 phone. Government Exhibit 3606 consists of call detail records and historical location information associated with the 2220 phone. Government Exhibits 3603 through 3606 are true and correct copies of records of Verizon maintained by Verizon and are records of regularly conducted activities of Verizon that were made at or near the time by or from information transmitted by someone with knowledge of information contained therein, kept in the course of regularly conducted activities of Verizon and made as a regular practice of the activities of Verizon.

It is further stipulated and agreed by and between the parties that the aforementioned Government Exhibits in this stipulation, which is Government Exhibit 9001, may be received in evidence at trial. And, your Honor, the government offers Government Exhibit 9001 and the exhibits listed therein.

THE COURT: Government Exhibit 9001, which is the stipulation, is admitted. It is evidence in this case, as are

the exhibits referenced in 9001.

(Government's Exhibits 9001, 3600-3607 received in evidence)

MR. GIANFORTI: Thank you, your Honor. If you can please pull up Government Exhibit 9004, Ms. Jung?

One moment, your Honor.

All right. This is another stipulation. I will skip the preamble again.

If called as a witness at trial, a record custodian for FedEx Services, FedEx, and for each of Government Exhibits 8000 through 8536 would testify that Government Exhibits 8000 through 8536 are true and correct copies of records of FedEx, maintained by FedEx, and are records of regularly conducted activities of FedEx that were made at or near the time by or from information transmitted by someone with knowledge of the information contained therein, kept in the course of regularly conducted activities with FedEx, and made as a regular practice of the activities of FedEx.

It is further stipulated and agreed upon by and between the parties that the aforementioned Government Exhibits in the stipulation, which is Government Exhibit 9004, may be received in evidence at trial.

Your Honor, the government offers Government Exhibit 9004 and all exhibits listed therein.

THE COURT: May I see the first page again, please?

Okay.

Government Exhibit 9004, which is the stipulation, is admitted as evidence in this case, and the exhibits referenced in that stipulation are also admitted as evidence in this case.

(Government's Exhibits 9004, 8000-8536 received in evidence)

MR. GIANFORTI: Thank you, your Honor.

Your Honor, the government calls John Rubino.

THE COURT: Leave the stip up for one minute.

All right. Thank you. You may take it down.

Good afternoon, sir. Would you please stand here and remove your mask?

DEPUTY CLERK: Good afternoon, please raise your right hand.

JOHN RUBINO,

called as a witness by the Government,

having been duly sworn, testified as follows:

DEPUTY CLERK: Please state and spell your name for the record.

THE WITNESS: John Rubino, J-O-H-N, R-U-B-I-N-O.

THE COURT: Thank you. Please sit down.

Sir, will you please pull the mic down so you're speaking directly into the microphone? Can you bend it? Thank you.

Mr. Gianforti.

DIRECT EXAMINATION

BY MR. GIANFORTI:

Q. Please do keep your voice up as I ask you questions, if you don't mind.

A. Okay.

Q. Thank you. Where do you work?

A. I work the Federal Bureau of Investigation.

Q. What's your position?

A. I'm a forensic accountant.

Q. How long have you been a forensic accountant with the Federal Bureau of investigation?

A. I've been a forensic accountant over here for three and a half years now.

Q. What did you do before you joined the FBI?

A. Prior, I was -- I worked at an accounting firm for two and a half years as an auditor.

Q. How far did you go in school?

A. Bachelor's in accounting.

Q. Mr. Rubino, did there come a time when you were asked to review some records in connection with your testimony today?

A. Yes.

Q. What were you asked to do?

A. I was asked to review bank records as well as create summary productions.

MR. GIANFORTI: Ms. Jung, can you please pull up

Government Exhibit 9003?

Your Honor, I'd like to read another stipulation into the record, if I could?

THE COURT: All right.

MR. GIANFORTI: All right. I will skip the preliminary paragraph again.

This stipulation reads:

If called as a witness at trial, a representative of WSFS Bank, WSFS, would testify that in or about September 2014, WSFS acquired the First National Bank of Wyoming. If called as a witness at trial, a record custodian for WSFS and for each of Government Exhibits 3700 through 3707 are true and correct copies of records of WSFS maintained, by WSFS, and are records of regularly conducted activities with WSFS that were made at or near the time by or from information transmitted by someone with knowledge of the information contained therein, kept in the course of regularly conducted activities of WSFS, and made as a regular practice of the activities of WSFS.

It is further stipulated and agreed by and between the parties that the aforementioned Government Exhibits in this stipulation, which is Government Exhibit 9003, may be received in evidence at trial.

Your Honor, the government offers Government Exhibit 9003 and all exhibits listed therein.

THE COURT: Government Exhibit 9003 is admitted into

evidence as are exhibit 3700 through 3707, which are referenced in that stipulation. They are also in evidence.

(Government's Exhibits 9003, 3700-3707 received in evidence)

MR. GIANFORTI: Thank you, your Honor.

Ms. Jung, can you please pull up 3706 and 3707?

BY MR. GIANFORTI:

Q. Mr. Rubino, do you recognize these documents?

A. I currently don't see anything.

Q. Oh, they're not up on your screen?

A. No. Oh, now I do.

Q. Hold on.

THE COURT: Is the jury seeing okay?

MR. GIANFORTI: These are in evidence. They were stipulated.

THE COURT: That's why I was asking if they're seeing them.

Q. Do you recognize these documents?

A. Yes, I do.

Q. What are they?

A. These are account statements for Equestology Inc. from WSFS bank.

Q. Have you seen these records before?

A. I have.

Q. Did you summarize these records at the government's

request?
A. I did.
MR. GIANFORTI: Okay. Ms. Jung, can you now please pull up Government Exhibit 1318? This is in evidence pursuant to stipulation, Government Exhibit 9015.
Q. For the record, Mr. Rubino, these are records from the First National Bank of Wyoming that were seized from a storage unit controlled by Seth Fishman. Have you seen these records before?
A. I have.
Q. What are these?
A. These are account statements from the First National Bank of Wyoming for Equestology Inc. account.
Q. Did you summarize these records at the government's request?
A. I did.
Q. And you said these are for an account for Equestology Inc., correct?
A. Right.
Q. Are their names associated with Equestology Inc. just below that?
A. Yes.
Q. What are those names?
A. It's Seth Fishman and Lisa Ranger.
Q. And is there an address associated with this account?

A. Yes. It's 125 Jennifer lane, Felton, Delaware.

MR. GIANFORTI: Ms. Jung, can you actually pull up 3706 and 3707 just briefly?

Q. Mr. Rubino, is there a company associated with these -- with this account?

A. I'm sorry?

Q. Is there a company associated with this account?

A. Yes. Equestology Inc.

Q. Are there names associated with this account?

A. Yes. Seth Fishman and Lisa Giannelli.

Q. And do you see an address in Delaware associated with these accounts?

A. Yes. It's 125 Jennifer Lane, Felton, Delaware.

Q. Thanks very much.

MR. GIANFORTI: Ms. Jung, can you please pull up Government Exhibit 3700 and turn to the second page?

If I may approach, your Honor? I'm going to hand a copy to the witness in hard copy.

THE COURT: Sure. Did you give it to Mr. Fasulo? Do you have a copy?

MR. FASULO: Yes, I do.

THE COURT: Thank you.

BY MR. GIANFORTI:

Q. All right, Mr. Rubino. If you flip through those documents -- have you seen them before?

A. Yes, I have.
Q. What do these documents appear to; be?
A. These are account opening documents.
Q. Associated with which account?
A. Associated with the First National -- these are from the First National Bank of Wyoming, and it's the account for Equestology. Additional customer names are Seth Fishman and Lisa Giannelli.
Q. Okay. Thank you.
MR. GIANFORTI: Ms. Jung, can you please go to page 1 of this document? All right. And can you blow up underneath where it says authorized persons?
Q. Mr. Rubino, based on this document, who appears to be the authorized persons associated with this account?
A. Seth Fishman and Lisa Giannelli.
Q. Who appears to be the corporate secretary for Equestology according to this document?
A. It appears to be Lisa Giannelli.
Q. And based on this document, when does it appear this account was opened?
A. 11/7/2011.
Q. So around November 7, 2011?
A. Correct.
MR. GIANFORTI: Ms. Jung, can you please go to page 3 of this document?

Q. Mr. Rubino, looking at the very top of this document, what kind of form does it appear to be?
A. This is an enhanced due diligence for high risk customers.
Q. And do you see a company name written in the upper right-hand corner in what appears to be handwriting?
A. Yes.
Q. What is that?
A. It's Equestology.
MR. GIANFORTI: Ms. Jung, can you please zoom in on lines six and seven of this document?
Q. Do you see line six, Mr. Rubino?
A. Yes.
Q. What is the business type that is listed here?
A. It's listed as horse meds.
Q. And do you see line seven there?
A. Yes.
Q. What is the business' primary customer trading area listed here?
A. It's racing horses.
Q. All right.
MR. GIANFORTI: All right. And, Ms. Jung, can you please go to page 5?
Q. Mr. Rubino, what does this document appear to be?
A. It's a certificate of incorporation for Equestology Inc.
MR. GIANFORTI: Can you please zoom in on where it

says second?

Q. Mr. Rubino, what is the address associated with Equestology according to this document?

A. The address is 125 Jennifer Lane, Felton, Delaware.

MR. GIANFORTI: All right. And, Ms. Jung, if you can then zoom out and zoom in on the very bottom where the signature is?

Q. Mr. Rubino, who appears to be the incorporator of Equestology Inc.?

A. It's Lisa Ranger.

Q. And when is this document dated?

A. December 21, 2006.

MR. GIANFORTI: Okay. Ms. Jung, can you go to page 6 of this document?

Q. All right. Mr. Rubino, what does this document appear to be?

A. This is a signature card for the Equestology Inc. account with Seth Fishman and Lisa Giannelli.

Q. And do you see where it says signatures of authorized signers?

A. Yes.

Q. Who appears to be the authorized signers for this account?

A. It's Seth Fishman and Lisa Giannelli.

MR. GIANFORTI: Okay. And, Ms. Jung, if you can please zoom in on the bottom part of this document?

Q. Is there an address here associated with Lisa Giannelli?
A. Yes.
Q. What is this address?
A. It's 125 Jennifer Lane, Felton, Delaware.
MR. GIANFORTI: All right. You can take this down. Thank you.
Q. All right. So, Mr. Rubino, turning back to the WSFS Bank statements that you reviewed and summarized, what time period was covered by those statements?
A. The time period was January 2015 to -- I believe it was five years. So it was January 2015 to December 31st, 2019, with a five-month gap in between.
Q. And when was that gap?
A. The gap was August 2018 to December 2018.
Q. So other than that five-month gap, you reviewed essentially five years' worth of account statements for the WSFS Equestology account?
A. Correct.
Q. All right. For that time period, Mr. Rubino, what was the total amount of deposits into the Equestology account?
A. The total amount of deposits were approximately 4.5 million.
Q. How were those deposits made principally?
A. They were typically made in -- via merchant sales as well as checks.

MR. GIANFORTI: Okay. Ms. Jung, can you please pull up Government Exhibit 1304, which is in evidence, and go to Page 15 of that document?

I'm sorry. I think I have that wrong -- it's Government Exhibit -- I think it's -- I think it's 3704. Apologies. Yes, thank you. And please go to Page 15.

Can you please zoom in on the third check from the top?

All right. This document is in evidence, and I'm going to read certain information into the record.

This is a check made out to "cash" from the Equestology account made out by a John J. Sheehan of 355 Guymard Turnpike, Middletown, New York 10940. It is stated December 3, 2014, and made out in the amount of $200. In the memo line it reads "bleeder pills" with the number 150 circled.

Ms. Jung, can you go to page 3 and zoom in on the third check? I'm going to read certain information into the record from this as well.

This is another check made out by John J Sheehan of 335 Guymard Turnpike, Middletown, New York 10940. The check is dated May 19, 2015. It's made out to "cash" in the amount of $80. The memo line reads "bleeder pills." And you can take that down. Thank you.

BY MR. GIANFORTI:

Q. Mr. Rubino, in reviewing the WSFS account statements for

the Equestology account, did you see any payments that went to somebody named Lisa Giannelli or Lisa Ranger?

A. I did.

Q. How were those payments made principally?

A. They were made principally through check.

MR. GIANFORTI: I will ask Ms. Jung to pull up for you but not for the jury Government Exhibit 19000.

Q. Mr. Rubino, do you recognize this document?

A. I do.

Q. What is it?

A. This is a summary chart of Lisa Giannelli payments made out of the Equestology Inc. WSFS bank account, with the last four digits 4901.

Q. For what time period?

A. For the time period of January 2015 to December 31, 2019, with that five-month gap in between.

MR. GIANFORTI: Your Honor, the government offers Government Exhibit 19000 as a demonstrative exhibit.

MR. FASULO: No objection.

THE COURT: All right. It will be received as a demonstrative exhibit, which means it's a summary of information obtained from other documents that are in evidence.

(Government's Exhibit 19000 received in evidence)

MR. GIANFORTI: Thank you, your Honor.

If we could publish that for the jury, Ms. Jung?

Q. All right. Mr. Rubino, based on your analysis, how much money did Ms. Giannelli receive from the WSFS account in 2015?
A. She received $143,542.
Q. How about 2016?
A. $200,730.
Q. 2017?
A. $184,266.
Q. 2018?
A. $86,181.
Q. And you testified earlier that 2018 has a five-month gap; is that right?
A. Correct.
Q. What was the total for 2019?
A. Total for 2019 was $172,243.
Q. And over this five-year period, what was the total amount of money that Lisa Giannelli received from this account minus the five-month gap from 2018?
A. The total was $786,964.
MR. GIANFORTI: You can take that down. Let's turn now to the analysis. We'll turn now to his analysis of the banks statements from the First National Bank of Wyoming.
Q. Mr. Rubino, what time period did those records reflect?
A. Those records reflected February 2009 to November 2009 with the slight gap, I believe -- approximately like a four- to five-day gap in between.

Q. Did you see any payments from this account that went to someone named Lisa Ranger or Lisa Giannelli?
A. I saw payments that went to Lisa Ranger.
Q. How were those payments made principally?
A. They were made via check.
Q. I'm now going to show you what's been marked for identification as Government Exhibit 19001, not to be displayed to the jury.

Sir, do you recognize this document?

A. Yes.
Q. What is it?
A. This is an account summary statement. It's detailing the payments to Lisa Giannelli over the time frame of 2001 -- I mean the time frame of February 2009 to November 2009, with that slight five-day gap in between.
Q. Okay.
A. For the account Equestology Inc.
Q. Did you prepare this table?
A. I did.
Q. Would it be helpful to you in testifying today?
A. Yes.

MR. GIANFORTI: The government offers 19001 as a demonstrative exhibit as well.

MR. FASULO: No objection.

THE COURT: All right. It will be received as a

demonstrative exhibit.

I will instruct you further about demonstrative exhibits at the end of the case, but that means this is a summary of information obtained from other documents. Those documents are in evidence; this is just a summary of that information, which was prepared by this witness to aid him in summarizing for you other evidence.

(Government's Exhibit 19001 received in evidence).

THE COURT: Mr. Gianforti.

MR. GIANFORTI: Ms. Jung, if you haven't already, can you publish that for the jury?

BY MR. GIANFORTI:

Q. Mr. Rubino, based on your analysis, how much money did Ms. Giannelli receive from the First National Bank of Wyoming account in 2009?

A. 133,698.

Q. Mr. Rubino, in preparing to testify today, did you review any of Lisa Giannelli's personal bank account records?

A. No, I did not.

MR. GIANFORTI: No further questions.

THE COURT: Mr. Fasulo.

CROSS-EXAMINATION

BY MR. FASULO:

Q. Good afternoon, agent.

A. Good afternoon. I'm not an agent. I'm a forensic

accountant.

Q. Good afternoon. Thank you.

MR. FASULO: I want the government to publish Government Exhibit 3700 again. And if we could go to page -- I think it's page 2 -- 3, page 3. Next page. Next page. There we go.

Q. Do you remember being asked some questions about this document?

A. Yes.

Q. And you stated that Lisa Ranger was incorporated. Do you understand what that means or what that is?

A. What was the question specifically?

Q. You stated that on the bottom there it indicates that Lisa Ranger -- I believe Ranger, was the incorporator. Do you understand what that is or what that means?

A. Not specifically.

Q. Okay. And you also had a chance to review this document before coming to court today?

A. I had.

Q. And is it fair to say there's nothing in this document that indicates the share distribution of this company as it relates to any of the shareholders; is that correct?

A. Correct.

Q. And there's nothing in this document that indicates that Lisa Ranger is a shareholder of Equestology Inc; is that

correct?
A. Correct.
Q. Now, you also said you did analyses of two banks -- of certain statements for specific periods of time; is that correct?
A. Correct.
MR. FASULO: If we could put the summary sheet up for Bank of Wyoming?
MR. GIANFORTI: Just the Wyoming one?
MR. FASULO: Yeah.
Q. You prepared this sheet, correct?
A. Correct.
Q. You prepared this sheet from bank documents that you had accessible to you, correct?
A. Correct.
Q. And they were bank documents regarding the account of the First National Bank account of Equestology Inc; is that correct?
A. Correct.
Q. And at the end of the day, these numbers reflect the amount that was given to Lisa from this account of $133,698.56, correct?
A. Correct.
Q. You did not review her personal taxes, right?
A. No.

Q. And you didn't review any deductions that she took regarding this income?
A. I did not.
Q. Right. And that was the only year you did this analysis from the First National Bank of Wyoming?
A. Correct.
MR. FASULO: Can we show the other summary sheet, please? Thank you.
Q. Again, you had an opportunity to look at bank documents for the year of 2015, 2016, 2017, 2018, 2019; is that fair to say?
A. Correct.
Q. And in one of those years there was a gap, right?
A. Yes.
Q. That's because you couldn't get those bank statements, or you didn't have them?
A. Yeah. Didn't have them.
Q. The analysis you did you looked at all of the checks that were made out of that account that were directly made to Lisa -- at that time, Lisa Giannelli, correct?
A. Correct.
Q. And you were able to identify the amount of money that Lisa Giannelli received from that account, correct?
A. Correct.
Q. What was the five-year total revenue that was disclosed in that account; if you recall?

A. I don't know what the total revenue was. The only thing I could attest to was the total deposits in that time frame was 4.5 million.
Q. I'm sorry?
A. Was approximately 4.5 million.
Q. Over that whole period of time?
A. Correct.
Q. Over that whole period of time you concluded that Lisa Ranger received $786,964.95?
A. Correct.
MR. FASULO: Nothing further, Judge. Thank you.
THE COURT: Any redirect?
MR. GIANFORTI: Yes, just briefly.
REDIRECT EXAMINATION
BY MR. GIANFORTI:
Q. Mr. Rubino, Mr. Fasulo just asked you about your analysis of the WSFS -- I'm sorry. It's a difficult acronym. The WSFS account and the total amount of deposits that were received in that account over that five-year period minus that gap; do you remember that?
A. Yes.
Q. And I think you testified both when I asked you and when Mr. Fasulo asked you that the total amount of deposits were approximately $4.5 million over that five-year period?
A. Correct.

Q. Did the government ask you to assess the profits of Equestology?

A. No.

Q. In other words, did the government ask you to assess revenue minus costs?

A. No.

Q. So when you looked at those bank records, you were solely looking at the amount of deposits that came in, right?

A. Correct.

MR. GIANFORTI: No further questions.

THE COURT: Thank you. Mr. Fasulo, anything?

MR. FASULO: Just one question, Judge.

Can the government can publish a deposit slip -- let me see the number. I think it was 3701.

THE COURT: Did you say 3701?

MR. FASULO: I thought it was, but I'm looking it up.

THE COURT: Oh.

MR. FASULO: Just to save time, if I may, one moment, Judge.

3704. Thank you.

RECROSS EXAMINATION

BY MR. FASULO:

Q. Mr. Rubino, as part of your analysis, you did look -- you just testified on redirect that you looked at the deposits, correct?

A. Right.
Q. And was this one of the deposits that you saw in your analysis?
A. It must have been at some point.
Q. Well, did you have a chance to look at the check?
A. Yes.
Q. And you see on the back of the check, is that indication that the -- this check was deposited into that account, as far as you know as an accountant? Let me direct your attention --
A. Yes.
Q. So when you talked about revenue, this would have been reflected in the total amount of -- when you talk about deposits, this would have been reflected in those deposits, correct?
A. Correct.
MR. FASULO: Nothing further, Judge.
THE COURT: Thank you.
MS. MORTAZAVI: Nothing further, your Honor.
THE COURT: Thank you very much, sir. You can step down with the thanks of the Court.
THE WITNESS: Thank you.
(Witness steps down)
THE COURT: The governments next witness?
MR. GIANFORTI: Your Honor, the government calls Conor Flynn.

THE COURT: All right.

MR. GIANFORTI: I'll read a couple of stips before we get to Conor Flynn if that's all right.

THE COURT: All right.

MR. FASULO: Your Honor, I am not asking the preamble to be, read but I would like the Court to remind the jury this is an agreement between the government and the defense.

THE COURT: When the government is offering these stipulations, he is not reading into the record the very first paragraph which says it's agreed by and between Damian Williams, who's the United States Attorney for the Southern District, and the two attorneys here representing the government and the other side. So this is a binding agreement between the parties, and it is evidence.

Go ahead, Mr. Gianforti.

MR. GIANFORTI: Ms. Jung, can you please pull up Government Exhibit 9014?

All right. This is a stipulation where I'll once again skip the preamble.

If called as a witness at trial, a law enforcement agent with United States Customs and Border Protection, CBP, would testify that Government Exhibits 18000 through 18001 are true and correct copies of records maintained by CBP with respect to Seth Fishman's United States border crossings from in or about October 1, 2011, through in or about January 9,

2020.

In our records of regularly conducted activities of CBP that were made at or near the time by or from information transmitted by someone with knowledge of the information contained therein, kept in the course of CBP's regularly conducted activities, and made as a regular practice of CBP's activities. It is further stipulated and agreed by and between the parties that the aforementioned Government Exhibits in the stipulation, which is Government Exhibit 9014, may be received in evidence at trial.

Your Honor, the government offers Government Exhibit 9014 and the exhibits listed therein.

THE COURT: All right. Exhibit 9014 is in evidence, as are exhibits 18000 and 18001, which are admitted pursuant to this stipulation, in other words, by agreement of the parties. Those two exhibits will come into evidence.

(Government's Exhibits 9014, 18000, 18001 received in evidence)

THE COURT: Is there another stipulation?

MR. GIANFORTI: There's one more, your Honor.

Ms. Jung, can you please pull up government exhibit 9016?

All right. Again, skipping the preamble.

If called as a witness at trial, Howard Taylor, Taylor, would testify that Government Exhibit 16000 reflects

true and accurate copies of records that Taylor maintained with respect to Equestology. It is further stipulated and agreed by and between the parties that the aforementioned Government Exhibits and this stipulation, which is Government Exhibit 9016, may be received in evidence at trial.

Your Honor, the government offers Government Exhibit 9016 in the exhibits listed therein.

THE COURT: Do you want to go back to the first page, please? It would help if you gave me a copy.

MR. GIANFORTI: I apologize. I thought you had a collection. We can hand you up one.

THE COURT: They're over there.

Again, this stipulation is in evidence, as is the exhibit -- there's only one exhibit -- 16000.

MR. GIANFORTI: That's right.

THE COURT: Is also received into evidence. That's all right.

(Government's Exhibits 9016 and 16000 received in evidence)

THE COURT: All right. Thank you.

MR. GIANFORTI: Thank you, your Honor. The government calls Conor Flynn.

THE COURT: Is Mr. Flynn here?

MR. GIANFORTI: The agent will bring him in, your Honor.

THE COURT: He's getting him. Thank you.

All right, sir. If you would stand behind the stand and take your mask off, please?

Ms. Dempsey.

CONOR FLYNN,

called as a witness by the Government,

having been duly sworn, testified as follows:

DEPUTY CLERK: Thank you. Please state and spell your name for the record.

THE WITNESS: Conor Flynn, C-O-N-O-R, F-L-Y-N-N.

DEPUTY CLERK: Thank you. Please be seated.

THE COURT: You have a microphone in front of you. Please adjust it down so it's pointed toward your mouth, and try to speak into the microphone when you're answering questions.

THE WITNESS: Yes, your Honor.

THE COURT: Mr. Gianforti.

DIRECT EXAMINATION

BY MR. GIANFORTI:

Q. Thank you. And just try to keep your voice up as we go.

A. Okay.

Q. How old are you, sir?

A. 32 years old.

Q. Where were you born?

A. Attleboro, Massachusetts.

Q. How far did you go in school?

THE COURT: Let's slow down a little bit. Okay?

MR. GIANFORTI: Okay.

Q. What do you currently do for work?

A. I graduated high school. I didn't answer that question.

Q. Oh, I'm sorry.

And what do you currently do for work?

A. I drive a furniture truck for a furniture company.

Q. Where are you living currently?

A. I'm living in Durham, Michigan.

Q. Prior to delivering furniture, what did you do for work?

A. I was a horse trainer and assistant horse trainer for Richard Banca.

Q. Who is Richard Banca?

A. He is a trainer that is -- was out of Middletown, New York.

Q. Was Mr. Banca based at a particular facility?

A. Mount Hope Training Facility.

Q. Do you know what county in New York that's in?

A. I believe it's Orange.

Q. When did you start working with Richard Banca?

A. Early 2015.

Q. And how did you get that job?

A. We shared a mutual owner client, and I trained some horses on my own. So when I kind of stopped training, went out of business, per se, I delivered some horses to Mr. Banca, and he

offered me a job.
Q. What kind of horses did Mr. Banca train?
A. Standardbred racehorses.
Q. What is a standardbred racehorse?
A. A standardbred is a breed of a horse that races, and it pulls a sulky or cart, as, per se, the thoroughbred, the jockey would be on the horse's back.
Q. What kind of horses have you worked with primarily in your career?
A. Standardbreds.
Q. Mr. Flynn, what is the job of a horse trainer?
A. Just the day-to-day care of horses, make sure they're exercised, fit, in good condition, make sure the help is doing all the work, classification of horses, dealing with owners, clients, billing, stuff like that.
Q. What's the job of an assistant horse trainer?
A. Just to assist the trainer, more with the day-to-day care, exercising, making sure the help is doing what they're supposed to do, arranging rides to racetracks, making sure there's transportation, stuff like that.
Q. Are you familiar with the role of a groom?
A. Yes.
Q. What is the role of a groom?
A. That would probably be like the lowest level in the hierarchy where they would just do basic care; clean stalls,

tack up horses, stuff like that, bathe them.
Q. And in terms of the hierarchy in a barn, let's say, how do those various roles rank?
A. Like I said, I would assume the groom would be the lowest, and he may have some exercise riders or people that jog horses, I would say, and then an assistant trainer and a trainer, I would say.
Q. Who does the trainer ultimately report to?
A. The trainer ultimately reports to the owners or the clients that own the horses.
Q. And is the owner responsible for paying all those people in the organizational tree, so to speak?
A. The owner would pay the trainer, and then the trainer would pay his employees.
Q. So the trainer does the actually hiring; is that fair to say?
A. The trainer would do the actual hiring, yes.
Q. Mr. Flynn, when did you start working with racehorses for the first time?
A. I would say around 2006.
Q. Where was that?
A. In Plainville, Massachusetts.
Q. And what did you do?
A. I was a groomer or stall cleaner.
Q. How did you get involved -- how did you get that job?

A. I had a friend I went to school with that had a job, and I went with him on weekends and started when I was in high school just working weekends.
Q. How long did you -- how long were you a groom in Massachusetts?
A. I would say through the later years of high school, two years, and then I moved to New Hampshire after high school in 2008, and after that I went to New York.
Q. What did you do in New Hampshire?
A. I was a groom. Same thing.
Q. How long did you do that for?
A. Just one summer there. The summer of 2008.
Q. After you were done -- after the summer of 2008, where did you go?
A. I believe I went to New York after that.
Q. Whereabouts in New York?
A. Saratoga.
Q. What's in Saratoga?
A. A racetrack, Saratoga Harness Track.
Q. Who did you work for there?
A. I worked for a few people. Rob Mangiori [ph], Mark Beckwith, and I also trained a few horses on my own.
Q. What was your role when you were in Saratoga?
A. I would say I was more like a groom or exercise rider, more just exercising horses.

Q. And did there come a time when you started racing in New Jersey?
A. Yes.
Q. When was that, approximately?
A. I would say on and off, you know 2009, 2010. Saratoga was closed in the winter, so I used to go down to New Jersey.
Q. Did your time in New Jersey overlap with your time in Saratoga?
A. Yeah. I would go back and forth.
Q. And what did you do in New Jersey, specifically?
A. I worked a little bit there, and I also trained -- I started training more horses down there.
Q. And did there come a time when you moved to Ohio?
A. Yes. I believe that was late 2013, early 2014.
Q. And what was your role in Ohio?
A. I was a trainer.
Q. While you were living in Ohio, did you also race in Kentucky?
A. Yes.
Q. Did you engage in horse training in Kentucky?
A. Yes. I would ship my horses from Ohio to -- some horses down to Kentucky to race.
Q. And after -- well, what, if anything, did you do after your time in Ohio in Kentucky?
A. Well, after that, I would have proceeded to work for

Mr. Banca.

Q. Okay. Sir, do you still work for Richard Banca?

A. No.

MR. GIANFORTI: Just one moment, your Honor.

Q. Mr. Flynn, is it fair to say that you worked in total -- you've worked with racehorses over a decade; is that fair to say?

A. Yeah, I would say that.

Q. Did you have to be licensed to work with racehorses during that time period?

A. Yeah. Every track you would go to, you'd have to be licensed.

Q. Are you familiar with the United States Trotting Association?

A. Yeah. The USTA, like --

Q. Go ahead --

A. -- the governing body, I would say, over harness racing.

Q. You said sometimes it's referred to as the USTA?

A. Yes.

Q. And it has a national scope, is that what you said?

A. Yeah. I would say it would be like the governing body.

Q. Governing body for what?

A. Harness racing.

Q. Is there a separate governing body for thoroughbred racing, as far as you know?

A. I believe so. I'm not too familiar with the thoroughbred side.
Q. Does the USTA issue licenses?
A. Yes.
Q. What kinds of licenses?
A. Owners, trainers, and drivers would have to be licensed through the USTA before they could get licensed by the state race commission.
Q. Have you ever held a license with the USTA?
A. Yes.
Q. What kind of license?
A. An owner's license and also a trainer's license.
Q. When did you get your trainer's license?
A. I would say around 2009.
Q. When did you get your owner's license?
A. Either late 2008, early 2009.
Q. How does one go about getting a license with the USTA?
A. Well, you would have to take a written test where there's questions, and then upon passing the written test, there would be a practical test where you would go to the racetrack and there would be somebody -- some representative from USTA would watch you in a practical exam.
Q. And what subjects, if you recall, were covered by the written examination?
A. Equipment, there were some rules, basic horse care, stuff

like that.
Q. And what was the test format; multiple choice, essays?
A. I believe it was multiple choice.
Q. All right. And you mentioned that the practical test involved harnessing a horse and racing it a bit?
A. Yeah. Like exercising it or training it a mile.
Q. Were there any other components to the practical exam you can recall?
A. Not that I can recall.
Q. Mr. Flynn, if you want to work with racehorses in a particular state, do you need a license from that state as well?
A. Yes. You would have to be licensed in each particular state also.
Q. All right. And we were talking about a number of states a moment ago. Have you ever held a trainer's license in Massachusetts?
A. Yes.
Q. How about in -- I think you said you were in New Hampshire. Did you have in New Hampshire?
A. I believe I just had a groom's license there.
Q. Did you have a trainer's license in New York?
A. Yes.
Q. New Jersey?
A. Yes.

Q. Ohio and Kentucky?
A. Yes.
Q. Did you have one in Pennsylvania?
A. Yes.
Q. Any states I missed?
A. I believe that's it.
Q. Okay. So let's use New York as an example. How did you go about getting your trainer's license in New York State?
A. Well, you just go to the track and fill out an application. It will be reviewed by the judges there, and then they would issue you a license.
Q. Do you have to have your USTA license first?
A. You would have to put your USTA number if you were an owner, trainer, or driver.
Q. Got you. When did you get your trainer's license in New York State?
A. I believe around 2009.
Q. Is that when you moved to Saratoga?
A. Yes.
Q. During the years that you worked with racehorses, did you come to have an understanding of different states' rules around the use of medication on racehorses?
A. Yeah, I had an understanding about the rules.
Q. Did you come to have an understanding of the penalties for violating those rules?

A. Yeah, I had an understanding.
Q. What were some of those penalties?
MR. FASULO: Objection.
THE COURT: Basis?
MR. GIANFORTI: If he knows.
THE COURT: What's the basis of the objection?
MR. FASULO: The correction, Judge. If he knows.
THE COURT: Can you only testify to what you know. If your answer is you don't know, that's your answer. That's true with every question.
MR. GIANFORTI: I'll ask it again.
Q. What were some of the penalties associated with violating the rules around administering medications to racehorses as you -- to the best of your knowledge?
A. They would vary for the lower level, like, therapeutic-type drugs, it could be a small fine and a number of days' suspension. And if you got to a higher class of drug, it could be up to 10 years and up to 10,000.
Q. Sir, are you familiar with the concept of purse money?
A. Yes.
Q. What is purse money?
A. That would be the money that you would win during a race.
Q. Could you lose purse money if you violate rules?
MR. FASULO: Objection.
THE COURT: Basis?

MR. FASULO: Speculation.

THE COURT: What's your understanding if you violated the rules, could you lose purse money?

THE WITNESS: Yes. The purse would have to be returned.

Q. And, in general, how did you come to have an understanding of the rules of each state that you raced in?

A. There was -- they were posted, the fines and suspensions, so you could see it online who got fined and who got suspensions. You could review them.

Q. Is that something you personally reviewed from time to time?

A. I reviewed them from time to time, yes.

Q. Were the rules and regulations posted elsewhere physically anywhere?

A. They were posted at the racetracks also.

Q. Okay. Mr. Flynn, in the State of New York, are there drugs that are prohibited outright for racehorses?

A. I believe that you're not supposed to administer to a horse on race day.

Q. Okay. How about are there any rules -- to the best of your knowledge, are there any rules in New York State that prohibit the administration of a substance completely regardless of whether it's race day or not?

MR. FASULO: Objection. Foundation.

MR. GIANFORTI: If he knows.

THE COURT: To the best of your knowledge. Overruled. You can answer.

A. I would say you would never be allowed to administer, like, Epogen or a blood builder.

Q. What's your understanding of what a blood builder is?

A. My understanding would be it would build a horse's red blood count to obviously carry more oxygen so they wouldn't get as tired fast.

Q. Would you consider a blood builder to be a performance enhancing drug?

A. Yes.

Q. How come?

A. Because obviously it -- it builds -- they wouldn't get as tired as fast.

Q. Mr. Flynn, have you heard of the Food and Drug Administration, or FDA?

A. Yes.

Q. What's your general understanding of what the FDA does?

A. My understanding would be is they review drugs to make sure they're safe for -- to be distributed or sold.

Q. To the best of your knowledge, under New York rules, are you allowed to give racehorses non-FDA approved drugs?

A. I don't believe so.

MR. FASULO: Objection.

THE COURT: Foundation?

MR. FASULO: Relevance.

THE COURT: Overruled.

Q. You can answer the question.

A. I don't believe so.

Q. You don't believe you can sell non-FDA approved drugs for racehorses?

A. I don't believe so.

Q. And I believe --

MR. FASULO: I move to strike, Judge. "I don't believe so."

THE COURT: Do you know, sir?

THE WITNESS: No.

THE COURT: All right. The answer is stricken then.

Q. Okay. All right. In New York State, sir -- I believe you answered this a moment ago. Are you allowed to give racehorses any drugs on race day, to the best of your understanding?

A. No. You're not allowed to administer anything to a horse on race day.

Q. All right. Mr. Flynn, how could someone get caught for violating New York's rules around administering drugs to racehorses?

MR. FASULO: Objection.

THE COURT: Sustained.

Q. To the best of your knowledge, how could someone get caught

for violating New York rules around administering drugs to racehorses?

MR. FASULO: Objection.

THE COURT: Sustained.

Q. Mr. Flynn, are you familiar with state racing authorities?

A. Yes.

Q. Are you familiar with what they do?

A. Yes.

Q. To the best of your understanding, what are some of the things that state racing authorities do?

A. License and handle all the testing.

Q. What kind of testing?

A. They have prerace and postrace testing for horses that race.

Q. And when you say testing, what are they testing for, to the best of your knowledge?

A. I would say drugs that aren't allowed.

MR. FASULO: Objection. "I would say," Judge.

A. Drugs that aren't allowed.

THE COURT: Do you know?

THE WITNESS: Yes.

THE COURT: Overruled, then.

Q. As best you recall, how does testing work in the State of New York?

MR. FASULO: Objection. Time period.

THE COURT: Sustained.

Q. During the over -- during the decade-plus that you were a racehorse trainer, to the best of your understanding and recollection, how did drug testing work for racehorses in the State of New York?

A. Well, before the race, they would randomly do some prerace testing, which would test the horse's TCO2 levels, and usually after the race, the first and second horse that finished would be taken to a separate area, and they'd collect blood and urine.

Q. You mentioned TCO2 levels a moment ago. What do you mean by that?

A. Essentially, they'd be testing for baking soda.

Q. Why would a racing commission test for baking soda?

MR. FASULO: Objection.

THE COURT: Sustained.

Q. Why would one -- sorry.

What's your understanding of the uses of baking soda on a racing horses?

A. My understanding would be it would settle lactic acid in the horse's stomach, and they wouldn't get tired as fast.

Q. Do you consider baking soda to be a performance enhancing drug?

MR. FASULO: Objection.

THE COURT: Sustained.

Q. You said that your understanding is that baking soda breaks down lactic acid in a horse; is that correct?
A. That's what my understanding would be, yes.
Q. What's your understanding of why you would want to do that? Why would you personally want to do that?
A. Because I think it would -- a horse wouldn't get as tired as fast.
MR. FASULO: Objection.
THE COURT: Sustained.
Q. If you know, in your own knowledge, Mr. Flynn, what's your understanding of what baking soda does to a racehorse?
A. It settles lactic acid in their stomach so they wouldn't get as tired as fast.
Q. Are you familiar with a concept in racing called out-of-competition testing?
A. Yes.
Q. What is that?
A. Well, randomly, the racing commissions could come to your barn and test horses that were not racing.
Q. How frequently, if you know, or during your time as a racehorse trainer, the 10-plus years as a racehorse trainer, how frequently, if you know, would out-of-competition testing happen in the State of New York?
MR. FASULO: Objection.
THE COURT: Sustained.

You need to lay a better foundation.

MR. GIANFORTI: Okay. All right.

Q. During your time as a racehorse trainer, did you ever -- were any of the horses under your care ever the subject of out-of-competition testing?

A. Yes.

Q. Approximately how many times?

A. Approximately three times. They came to Mr. Banca's barn.

Q. Okay. What about during your time in other states? Do you recall any other out-of-competition testing?

A. No. I never had any other done.

Q. In the 10-plus years you were a trainer, about three times?

A. About three times, yes.

Q. All right. Mr. Flynn, to the best of your knowledge, are the general rules we've been discussing in New York more or less the same for all the states in which you held licenses?

MR. FASULO: Objection.

THE COURT: Sustained.

Q. All right. So for the states in which you were licensed, Mr. Flynn, did those states have a drug testing program for racehorses?

A. Yes.

MR. GIANFORTI: All right, your Honor. I know it's 4:30. This is actually a decent breaking point for me.

THE COURT: We'll break at this point. I'll remind

you that you remain under oath. So this evening, you may not talk to anybody, including the government lawyers, about the substance of your testimony.

THE WITNESS: Yes, your Honor.

THE COURT: If you please remain in your seat. Well, actually I'm going to excuse you at this point, with the thanks of the Court.

You remain under oath.

THE WITNESS: Thank you, your Honor.

THE COURT: And after he leaves, I will excuse our jurors. And if you would please then leave the area quickly because the jurors are going to be departing as well.

THE WITNESS: Yes, your Honor.

(Witness steps down)

THE COURT: All right. So I thank you all very much for your attention today. Please leave your notepads either on your seats or in the jury room when you are on your way out. I'll see you all tomorrow morning at 9:45. And I remind you, please do not research anything about the case, please don't talk to anybody about the case, about the witnesses, about what's gone on in the courtroom today, or about the subject matters of this trial. All right?

So I wish you all a good evening, and I'll see you tomorrow morning. Thank you.

(Continued on next page)

(Jury not present)

THE COURT: All right.

Mr. Gianforti and Ms. Mortazavi, is this your last witness?

MR. GIANFORTI: Overall?

THE COURT: Yes.

MR. GIANFORTI: No. After Mr. Flynn, I think it will likely be some combination of Adrienne Hall, Rita Noblett and Cynthia Cole.

THE COURT: Who are the last two witnesses?

MR. GIANFORTI: Rita Noblett is a representative of the Pennsylvania State Racing Commission, and Cynthia Cole is one of our experts, and I suspect that will take us all the way through tomorrow at a minimum.

THE COURT: Okay. All right.

Is there anything that we need to talk about from the government's point of view

MR. GIANFORTI: Not from the government, your Honor. Thank you.

THE COURT: Mr. Fasulo?

MR. FASULO: Nothing from the defense.

THE COURT: Thank you. Then I'll see everybody shortly before 9:45 tomorrow then. I'll see you a little bit before then. Thank you.

(Adjourned to May 3rd, 2022, at 9:45 a.m.)

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GOVERNMENT EXHIBITS